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Health Technology: Design of Bandage-Sized Wireless Sensors and Effect of Ambient Displays on Social Support and Diabetes Management

By

Akshay Mohan

B.Tech. Materials Science
Indian Institute of Technology – Kanpur, 2002

Submitted to the Program in Media, Arts and Sciences,
School of Architecture and Planning, in partial
fulfillment of the requirements for the degree of
Master of Science in Media Arts and Sciences
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Author: Akshay Mohan

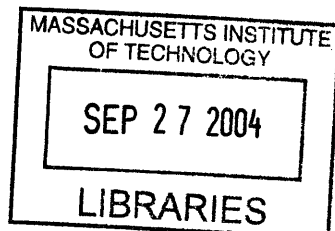
[Programs in Media Arts and Sciences
Massachusetts Institute of Technology
August 18, 2004]

Certified by: Rosalind W. Picard

Associate Professor of Media Arts and Sciences
Massachusetts Institute of Technology
Thesis Supervisor

Accepted by: Andrew B. Lippman

Chair, Departmental Committee on Graduate Studies
Program in Media Arts and Sciences
Massachusetts Institute of Technology



ROTC

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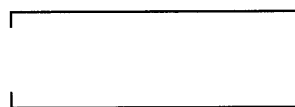
Abstract

Health-Zero refers to health technology design that focus on interaction with an individual as a whole to promote well-being. This thesis presents two explorations in the discipline. The first exploration involves the design of a wireless bandage-sized ECG sensor to create a personal and inter-personal network of health sensors. The second exploration designs and evaluates an ambient blood glucose level visualization and feedback system for diabetes self-care and social support, where the latter is provided by a friend or family member of an individual with diabetes. This thesis provides insight into using technology to enable an individual to leverage his environment and inter-personal relationships for self-care and prevention.

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By

Akshay Mohan



Thesis Advisor

Rosalind W. Picard

Associate Professor of Media Arts and Sciences
Programs in Media Arts and Sciences
Massachusetts Institute of Technology



Thesis Reader

Joseph A. Paradiso

Associate Professor of Media Arts and Science
Programs in Media Arts and Sciences
Massachusetts Institute of Technology



Thesis Reader

Alex P. Pentland

Toshiba Professor of Media Arts and Sciences
Programs in Media Arts and Sciences
Massachusetts Institute of Technology

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'It is a great adventure to contemplate the universe beyond man, to think of what it means without man..... to then turn the objective eye back on man viewed as matter, to see life as part of the universal mystery of greatest depth, is to sense an experience what is rarely described. It usually ends in laughter, delight in the futility of trying to understand.' – Richard P. Feynman

The past two years during the development of this thesis have been such a journey for me, I have been in a fantasy to contemplate about the universe and connect with it. At times the experience has been oscillating between the reality of life and its connection to the universe. There are people who have been with me on this journey, people who showed me the universe, people who help me keep in touch with reality and people who helped me make the connections.

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TO GOD

1 The Beginning

1.1 Introduction

A profound transformation is happening in the history of humanity. Technology is being used to create systems of increasing complexity, convergence and connectivity (Toffler 1970). Businesses are becoming globalized and focusing on providing a variety of function-specific products to consumers. Human capacity is increasingly being tested and challenged to differentiate through using these complex products. Demographically there is a rapidly aging population in industrialized and industrializing nations that is being diagnosed of and treated for chronic diseases. This need for diagnosis and cure is translating into increased demand for healthcare systems that emphasize diagnosis and disease management. This is increasing the cost of healthcare and ultimately reducing the effective treatment that the healthcare systems can provide.

Now that technological complexity is nearing the limits of current human capability and the healthcare system is under immense strain, it is time to change the focus of healthcare to wellness and prevention and assess the role of technology in promoting well-being.

This need for the change in the focus of healthcare and development of health technology for well-being has been reiterated and well documented. To cite a few examples, Proactive health (Timpka 2001) uses data from multiple sources to give individuals and communities information on means to improve their state of health and avoid health risk. There is significant industrial research to create health technologies that provide individuals an array of information of their physiological well-being (Intel 2004). Yet, the efforts have been marked with creation of healthcare devices that provide a specific functionality to an individual and interact with an individual as a sum of his or her parts, rather than as a whole. There have been no systematic efforts to analyze the influence of technology on the individual as a whole and use it as the basis for the design and evaluation of health technology.

Amidst this research, I propose a vision of Health-Zero: health technology design focused on interaction with an individual as a whole to promote well-being. I focus on a framework for health technology design and evaluation that uses existing innovations in technology and business to promote the well-being of an individual. The technological complexity can be redirected towards creation of individual-centric healthcare systems that provide an experience to an individual and not just serve a function. Here I use “experience” broadly to refer to the collective interaction of the individual along the different domains of interaction: affective, cognitive, interpersonal, moral and spiritual.

The level of analysis is directed both towards an overall design philosophy for health technology to provide an individual experience and towards specific explorations that provide insight into the interaction with health technology. I divide my thesis into three parts.

Part I: Tools

In Chapter 2 I present an integrated framework to understand the influence of technology on individual healthcare. The framework is used in Chapter 3 to present the relevant background literature and provide an overall perspective into the project.

Part II: Explorations

In Chapters 4 and 5 I present two of my own explorations in the design and evaluation of integrated health technology. The first exploration outlines the process of and final design of a wireless bandage-sized ECG sensor that creates a personal and interpersonal network health sensors. The second exploration (Chapter 5) designs and evaluates an ambient blood glucose level visualization and feedback system for diabetes self-care and social support. The chapters include analyses based on the domain areas of the explorations and from the perspective of integrated health technology design.

Part III: Conclusion

Chapter 6 describes the overall contributions of the thesis- both at the level of design of health technology and the innovation specific to the two explorations. It provides a list of core qualities that are essential to the Health-Zero approach. Finally, Chapter 7 discusses the future applications in the field of Health-Zero and considers the current state of health technology in the field.

2 Framework: Health-Zero

2.1 Introduction

Technology needs to interact with an individual as a whole- not just the different parts of an individual. I focus on developing a methodology for health technology design that considers interaction with this whole individual, a vision for integrated health technology: Health-Zero.

I present a conceptual framework to understand the influence of technology on individual healthcare. Towards this goal, I modify Wilber's 4-Quadrant model (Wilber 2000) to develop an integrated framework to understand an individual and his or her interaction with the environment. This framework is then interpreted in the domain of healthcare to describe the interaction between health technology and an individual. By no means complete, it encourages the reader to adopt an approach to technology design that considers an individual as a complete conscious whole with, and not just, an empirical system. This perspective benefits both: the designer and the user.

2.2 Integrated Framework

2.2.1 Individual Interacts

This thesis assumes that an individual can be modeled as a system that is completely and uniquely specified by its state. The individual belongs to a hierarchy- being composed of subsystems and being part of metasystems. Figure 2-1 gives an example of one possible hierarchy.

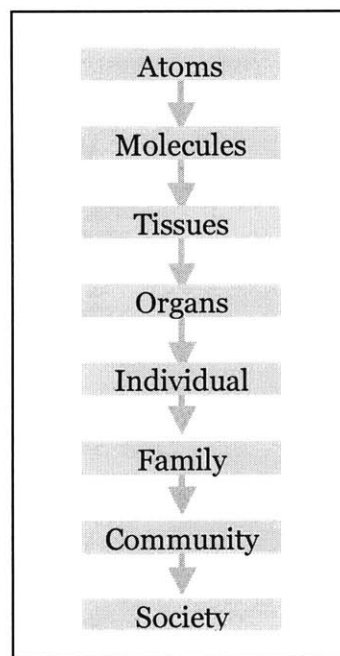


Figure 2-1 A Possible Hierarchy of Systems Involving an Individual

2.2.2 State Changes

The individual undergoes state transformation due to his or her interaction with the environment or due to changes within himself or herself. The state of an individual can be considered as the set of all properties associated with the individual at a given instant of time at a specific location. The space and time constraint are important to determine the context of the state. A modification of Wilber's 4-Quadrant Model can be used to classify the different properties that constitute the state. Wilber used the model to integrate findings and conceptual insights from different disciplines to provide a Theory of Everything (Wilber 2000). Based on the model, the different properties constituting the state of an individual can be classified by the domain of observation. The domain of observation determines the domain of the individual under consideration: affective, cognitive, moral, interpersonal or spiritual. The domains of observation are not independent of each other and should not be considered as independent dimensions. For example, a change in the emotional state of an individual changes his or her cognitive state as well. Each domain of observation can have different levels of observation. The level of observation determines the level of abstraction at which the individual is being observed: body, mind, soul or spirit. Figure 2-2 represents an individual according to the different domains and levels of observation. One can focus on a specific property in a specific domain of observation and at a specific level.

Level of Observation	Domain of Observation				
Spirit	Affective	Cognitive	Interpersonal	Moral	Spiritual
Soul					
Mind					
Body					

Figure 2-2 The Different Levels and Domains of Observation in an Individual

Each of the properties at a specific level of observation within a particular domain of observation can have four components (Figure 2-3) based on the mode of observation (Wilber 2000):

Individual Subjective	Individual Objective
Collective Subjective	Collective Objective

Figure 2-3 The Different Modes of Observation of an Individual

Here the 'individual' refers to the perspective of the patient or the individual user of health technology while collective 'collective' refers to systems and other people in the individual's environment. The 'subjective'

observations include perceived thoughts and feelings such as “I liked it” or “he did well” while the ‘objective’ observations tend to be measurements such as number of steps or a record of behaviors that your smart home environment observed you doing.

1. Individual Subjective Component: The subjective observation made by an individual of his or her property due to his or her consciousness.
2. Individual Objective Component: The objective empirical observation of a property of an individual made by the environment.
3. Collective Subjective Component: The subjective observation of a property of an individual made by the universe due to the individual being part of a larger system- a collective consciousness.
4. Collective Objective Component: The objective empirical observation made by the environment of a property of an individual due to the individual being part of a larger system.

Within each domain are four levels of observation, each with four components that reflect the mode of observation. Figure 2-3 provides a diagrammatic representation of the state of the individual based on the mode of observation.

It is important to note that the four components are manifestations of the same property and differ only in the mode of observation. Thus, a change in one of the components of the property changes the other components as well. For example, a change in the internal emotional state of an individual (individual subjective component) is reflected in the corresponding physiological change (individual objective component). Other individuals can understand this change if they have access to this change and share the same meaning for the particular emotion (collective subjective component). This collective understanding can also be sampled by making measurements of a community (collective objective component).

2.2.3 Influence of Technology

Technology plays a role in this state transformation by changing the individual, his or her environment or the interaction between individual and environment. Thus, the role of technology is multifold:

1. It can be used to change the form of interaction between existing systems and the constraints associated with the interaction. This changes the individual, the environment or the interaction between them.
2. It can be used to create new systems. This changes the environment and allows new interactions to occur between the individual and his or her environment. The new system can also be a channel of communication to interact with other entities in the environment.

The difference in the above two roles is small but philosophically important. When a new system is created using technology, the state associated with the system has different domains of observation and has the four components associated with each of the different domains. The

presence of different levels would be dependent on the level of abstraction of the created system. The system is capable of interaction with the individual in the different domains: affective, cognitive, interpersonal, moral and spiritual. The realization of the capability and the extent of interaction in the different domains depend on the level of complexity of the system.

2.3 Integrated Health

The above framework can be used to describe an integrated model of healthcare as it relates to individual well-being. Well-being can be considered as a desirable state (or a set of possible desirable states) of an individual. Disease can then be considered as a state transformation that takes an individual away from the state of well-being to a state of disease. Here it is neither necessary nor possible to discuss the definition of well-being as the definition differs according to time periods and regions. Thus every disease can be analyzed at different levels of observation in each of the different domains of observation. Each of the properties at a particular level and domain of observation will have four components depending on the mode of observation.

One can use the model of integrated healthcare to design health technology that considers specific diseases and the associated health transformations to determine the needs of the individual. This is discussed in the next section.

2.4 Integrated Technology

For a comprehensive and integrated solution we need to consider and focus on all the above changes and then focus on the needs that arise from each of the above transformations. For technology to be effectively used in designing systems that satisfy these needs, it is important to consider all the above state transformations and how an individual's interaction with the system would change the above example. Only then can one use technology to provide an experience to an individual, not just serve a specific function.

We can focus on one particular component of a domain of observation and design technology to address the need. For example, we may design technology that allows an individual to become more mobile. This would directly address the need along the cognitive domain of interaction and would produce effects on all the four components and different domains, even though the designer would have designed only according to the objective measurements he or she made. It is not possible to evaluate the influence of technology completely along the different dimensions but it is important to be aware of the relationships they have with each other and then focus on what is realizable based on current technology.

When designing technology for wellness, the individual needs to be an integral part of the process of the creation and use of the health technology. The health technology designer needs to recognize that every

individual is unique and thus so are individuals' interactions with technology. In short, every interaction between an individual and technology is a unique experience. This is an integral component of Health-Zero.

How can one design such an integrated technology that promotes well-being of an individual? How can one use the above framework to design and evaluate an integrated health technology? There are some of the questions that this thesis addresses.

2.5 Differentiated Thesis

I take a step forward towards Health-Zero, which uses the existing transformations in technology and business to promote the well-being of an individual. I explore how the complexity, connectivity and convergence of technology can be used to change the interaction of an individual with health technology along the different domains of observation: affective, cognitive and interpersonal. The explorations have their implications for the moral domain. These implications are briefly touched upon but a detailed analysis is beyond the scope of this thesis. My two explorations approach the design of integrated health technology along different axes: the use of individual vs the environment or their domain of interest: cardiovascular diseases vs diabetes. I present an overview of the two explorations and their grounding in the framework.

2.5.1 Exploration A: Bandage-Sized Wireless Sensors

My first exploration focused on using technology to augment the individual and the methodology adopted was of engineering design. The framework was used to present a design specification that used the available electronic components to create a sensor network that can improve the interaction of an individual with health technology along affective, cognitive and interpersonal domains of observation.

I explored the concept of a distributed sensor network of wireless bandage-sized sensors for wearable health applications. As a building block for the network, I made a wireless sensor for measuring and communicating ECG signals. I attempted to improve the cognitive domain of the individual by making him or her more aware of physiological state. The affective domain was improved through increased user comfort. At the same time, the sensor aimed to share this information with the environment to improve the interpersonal domain of the individual.

It was an important learning experience from the perspective of sensor design and communication but it lacked the real world testing that is so important in the design and evaluation of healthcare systems. This was due to a shift in thesis goals and the invasive nature of measurement of ECG signals using an electrode. My second exploration fulfilled the desire to have a real world evaluation.

2.5.2 Exploration B

My second exploration focused on using technology to make the environment a medium of expression and the methodology adopted was of scientific inquiry where a system was designed to test a hypothesis. The framework was used to design as well as evaluate a health technology system that can improve the interaction of the individual along the cognitive and interpersonal domain. Here the objective was to design and evaluate technology that could improve a clinical objective: diabetes self-care.

Specifically, I explored the effect of using ambient displays for visualization and feedback of health information. Towards that goal, I designed and evaluated a computer-based ambient blood glucose level visualization and feedback device and evaluated its effect on diabetes self-care. The device displayed the blood glucose level of an individual as a color rather than as the more traditional number. This color could also be shared with a friend or family member who could be instrumental in providing support to the person with diabetes. The system was evaluated in a user study with eight participants. It was hoped that participants' cognitive domain in diabetes care would improve by providing them with a visualization tool while their interpersonal domain would improve by the creation of a communication channel between the participants and their friend or family member.

The study was important in different ways. It highlighted the usability of the framework in a real-life clinical situation. It emphasized the affective power of a color as a medium of expression for healthcare information and the strong effect of culture in the interpretation of color. But most important of it all, it provided an insight into the way an individual interacts with technology and how the interaction becomes the basis of creation of value for the individual that is unique to him or her.

Table 2-5 presents the two explorations along some of the axes that were common to both them or that made them unique with respect to each other.

	Exploration A	Exploration B
Methodology	Engineering Design	Scientific Inquiry
Interest Areas	ECG signals Sensor Networks Wearables	Blood Glucose Level Diabetes Self-Care Social Support
Domain of Design	Affective Cognitive Interpersonal	Affective Cognitive Interpersonal
Domain of Observation	Affective Cognitive Interpersonal	Affective Cognitive Interpersonal Moral
Level of Observation	Body	Body Mind
Medium of Expression	Individual	Environment

Table 2-5 The two explorations and their properties

3 Perspective

3.1 Introduction

As an individual transforms, so does technology and its use. This transformation is reflected in the trends observed both in industry and in academia. I present the background research here for the reader to reflect on this trend in healthcare and develop a sense of the future- futuristic but placed in reality.

I present the background research in areas relevant to the thesis, academic as well as industrial (to the extent that the latter was made public) using the Health-Zero framework described earlier. This establishes the domains, levels and modes of observation present in the existing health technology field and provides an overall perspective on the explorations presented in this thesis. It gives a rationale for my explorations.

3.2 Overview

Healthcare is undergoing a dramatic transformation and this is particularly the case in the development of the field of health technology. The individual is becoming the epicenter of the development of health technology, with a focus on interaction in the different domains of observation. Changes in the healthcare belief structure are changing health technology design. The healthcare industry has been through three belief structures that can be characterized as the traditional belief structure, the transitional belief structure and the future belief structure.

In the traditional belief structure, the healthcare provider was considered responsible for the health of the individual through an approach of disease cure. The provider was the only source of medical diagnostics, feedback and information. The individual's role was passive patient and information receiver. Health technology was designed for the health care provider. The healthcare provider had the technological infrastructure and devices, and used those to get information and prescribe a treatment and medication for the individual. It was driven by clinical healthcare with its focus on the individual objective mode of observation. The technology focused on improvement in the cognitive domain of the individual. An important shortcoming of such an approach was that it did not typically take into account the internal cognitive or affective state of an individual except for when the disease was psychological.

In the transitional belief structure, the focus of healthcare shifted to disease management and the role of an individual became that of active patient in the maintenance of his or her disease. The healthcare provider was the primary source of care and medical diagnostics but no longer the only source of information. There was an active dialogue where the individual had a say in defining and choosing the treatment. There were two different foci: the healthcare provider and the individual. However,

the healthcare provider was still the focus for the design of health technology. The provider needed information over a period of time to help an individual manage the disease. The provider thus used infrastructure, provided the individual with devices, obtained information from those devices and had a dialogue with the individual about the treatment. Health technology was designed primarily for the physician with the aim to improve interaction between the physician and the individual. The technology was aimed towards improvement in the cognitive and the interpersonal domain like telemonitoring systems. Here the interpersonal domain was restricted to being between the individual and the physician. The dialogue between the individual and the physician occurred because the individual also had information. Technology from other domains - such as the internet - was adapted by the individual for use in healthcare. The individual here was the focus. The individual needed the information, the individual used his or her infrastructure to get the information and used it to have a dialogue with the physician.

In the future belief structure, the focus of healthcare changes to wellness and the role of an individual changes to being an active participant with the primary source of care in the individual's environment. The focus shifts to the individual being the producer and the receiver of information. He or she needs the information, uses the devices and gets the information. It is for him or her to effectively use this information by sharing it with the physician. The role of physician is to provide medical diagnostics and feedback. Health technology is designed for use by the individual in his or her environment: home, office, car or elsewhere. The technology is to provide an experience to the individual that spans the different domains of observation. Thus, there is an expansion in the focus from improvement in the cognitive and interpersonal domains to other domains: affective, moral and spiritual. One can see this trend emerging with technology that is designed to combine different domains of the individual. Extremity computing (Gerasimov 2003) aims to combine the affective and cognitive domain and uses games as a medium to make the individual more aware of his or her physiological signals and promote a healthy lifestyle. Relational agents (Bickmore 2003) combine the affective, cognitive and interpersonal domains to build a long-term bond with individuals to encourage them to exercise. Value based design (Kahn, Friedman 2003) proposes embedding value systems within health technology systems to prevent misuse of health information.

In the next section, I discuss background literature in the areas of health technology that is directly applicable to this thesis project- health technology related to wearable sensing, data visualization and social support.

3.3 Health Technology for Wearable Sensing

Health Technology in the field of wearable sensing has rapidly evolved from isolated wired sensors focused on measuring a single physiological parameter at a given instant of time to an interconnected network of sensors capable of continuous monitoring of multiple parameters. This

change has been due to two factors. The first factor is the change in the focus of healthcare from disease cure to disease management and finally to wellness. The second factor is technological progress in areas such as communication, sensing and algorithm design.

When the focus of healthcare was disease cure, a wearable sensor involved going to the hospital and wearing the sensor, like an ECG monitor. Individuals would go to the hospital, have the electrodes attached to their bodies and have their ECGs measured. Individuals did not own an ECG monitor. Here the healthcare provider needed the information, had the sensor and obtained the information. The focus of health technology was on the cognitive domain of observation.

As the focus of healthcare shifted to disease management, the second-generation of wearable sensing health technology developed, the holter monitor as an example. The physician would provide individuals with one so whenever he or she develops a symptom for a cardiovascular disorder, it would record his or her ECG for a specific time-period. This data can be later used by the physician to diagnose the specific cardiovascular disorder. Here the physician needed the information, the individual had the sensor and the physician obtained the information. The design of the wearable sensor was in the cognitive domain and the interpersonal domain. Here the interpersonal domain was restricted to the communication between the individual and the physician.

With the focus of healthcare shifting to wellness, the third generation of wearable sensors are being developed to fit the concept of wellness. A simple example is the heart chest straps that measure heart rates, usually while an individual is exercising. Wearable sensing is increasingly being designed for use by the individual in his or her own environment. Here individuals require the information, have the sensor and obtain the information. It is the individual's decision to use it.

Sensors are also being developed that are part of the environment (smart home). The concept of smart homes is not discussed in detail here but Stefanov (Stefanov, Bien et al. 2004) provides an excellent review. The third generation wearable sensors are evolving to provide continuous monitoring of different physiological parameters over long periods. In the table given below, the work is presented based on the form factor (system specification) and the different functionalities present in them: sensing, communication, processing and power (functional specification). Table 3-1 provides an overview of the different sensors based on the above classification.

Classification	Examples
Form Factor	Implantable (Meron 2000), Watch (Korhonen, Parkka et al. 2003) , jewelry (S. Rhee 1998; Healey 2000; Picard, Healey 1997), apparels (Park and Jayaraman 2003), worn as separate sensors (Polar 2004), (BodyMedia 2004)
Functionality: Sensing	Activity levels (Fitsense, 2004), heart rate sensors (Gerasimov 2003), skin conductance (Picard and Scheirer 2001), blood pressure monitor (OMRON 2004), breath-monitor (Jovanov, Raskovic et al. 2001)
Functionality: Communication	2.4GHz (R. W. DeVaul 2003), specialized protocols like Bluetooth (Warren 2002), ZigBee, 802.11, cellular networks, pagers to other frequency domains (Jovanov, Lords et al. 2003).
Functionality: Processing	PDA, Cellphones (Picard and Du 2002) Digital Signal Processors, Simple microcontrollers.
Functionality: Power	Battery powered, powered through body movements

Table 3-1 Overview of Different Wearable Sensors

Sensors are available in different forms including implants, watches (Korhonen, Parkka et al. 2003), jewelry (S. Rhee 1998), clothing (Park and Jayaraman 2003) and independent sensors. This has provided a base for wearable sensors that in the future could be used continuously for long time-periods. Power has been a major issue and battery life limits the continuous use of sensors. Sensors have also been developed that derive power from body movements (Paradiso, 2000)

Based on the communication architecture, the sensors differ in the use of the communication frequency (if they are wireless), the protocol for communication and the network architecture of the sensors. The communication frequency and protocol have varied from custom 2.4GHz (R. W. DeVaul 2003), specialized protocols such as Bluetooth (Warren 2002), ZigBee, 802.11 to lower frequencies such as 900 Mhz (Jovanov, Lords et al. 2003). There is an increased trend to use the unlicensed 2.4Ghz band or the existing network infrastructures like cellular networks (Picard and Du 2002) and pager networks (Ambient 2004). In most of the cases, the sensor connects to a base station. A major change has come in

the ability of the base station to connect to the different networks around it using the computing devices present in its environment such as the home computer. The base station itself is being morphed with mobile electronic devices that an individual uses for his or her digital needs. Thus from an earlier design that used custom boards, the new wearable sensors increasingly use PDAs, like Zaurus or iPAQ (Jovanov, Raskovic et al. 2001; Jovanov, Lords et al. 2003) and cell phones (Picard and Du 2002). This makes the system more integrated with the existing devices an individual may use and it makes it less susceptible to the hardware being obsolete.

Sensors are available for different measurements such as activity levels (Fitsense, 2004), heart rate sensors (Gerasimov 2003), skin conductance (Picard and Scheirer 2001), blood pressure monitor (OMRON 2004), breath-monitor (Jovanov, Raskovic et al. 2001).

The focus here is on ECG measurement sensors. The sensors can be classified in various ways: method of measurement of ECG signal, the form factor of the sensor or the various functionalities associated with it. Table 3-2 provides the different sensors present that can measure ECG signals or, more broadly, heart parameters. A review of the various methods of heart-rate monitoring can be found in (Bronzino 2000) and (Webster 1998). The earliest clinical examples of wireless telemetry of ECG signals were in the area of wireless radio telemetry for monitoring fetal heart rate and intrauterine pressure using a two-channel miniature radio transmitter (Neuman, Picconatto et al. 1970).

Project	Details
Every Sign of Life (Gerasimov 2003)	Data acquisition board that measures a 3-lead ECG using electrodes
Chest straps by different companies (Fitsense 2004), (Polar 2004)	A chest strap with 2 electrodes that provide 2-lead ECG data
LifeShirt System (Vivometrics 2004)	A shirt with embedded carbon electrodes and inductive plethysmographic sensors that analyze blood and respiratory flows.
SmartShirt (Sensatex 2004)	Sensors and circuitry embedded in an undershirt
Persimon (CSIRO, 2004)	Non-contact ECG

Table 3-2 Wearable ECG Sensors

At the time of my first exploration, there were few wireless ECG sensors capable of measurement of 3-lead ECG. However the need for effective home care solutions for medical monitoring of individual,s together with development in the area of wireless communications especially Bluetooth has led to a rapid development in the area of ECG sensing.

Although there is an increased trend towards connectivity of the sensors, the focus of this thesis research is the interaction between the individual, his or her inanimate environment and the caregiver. My first exploration

as described in Chapter 4 is a step in the design of a sensor network that breaks this connectivity divide using a wireless 3-lead ECG sensor. Can a wireless sensor be designed that measures 3-lead ECG? Can it be as small as a bandage? Can I connect it to other bandages? I designed a wireless 3-lead sensor that can communicate over a range of hierarchies of which an individual is a part to provide integrated health monitoring. The innovation I feel is not just in designing an ECG sensor but the consideration of the user of such sensors in real-life, which influences both personal and interpersonal communications.

3.4 Health Technology for Social Support

The interpersonal domain of an individual, specifically the domain of other individuals with whom he or she interacts (his or her social network) plays an important role in the health of the individual. The social support provided by such individuals can range from providing health information to being a caregiver (Wellman 1999). A majority of this health-related social support comes from close friends and family members, the physician or thematic communities (individuals with similar health problems or issues).

When the focus of healthcare was disease cure, the interpersonal domain relevant for clinical healthcare consisted of the interaction between the individual and the physician. Since the individual was a passive patient, the exchange of information involved the physician simply asking for symptoms and dispensing medication.

As the focus of healthcare shifted to disease management and the role of the individual increased, two different phenomena could be observed. Health technology was designed to improve the interaction between the physician and the individual. An example is telemonitoring systems. The individual needed to give the symptoms from home and the physician required the information. Therefore, a system was set up to provide a communication channel for such information. Here the focus was on communicating to the physician. Simultaneously the individuals adapted technology from other domains for use in healthcare. This increased the information available to the individual. For example, individuals and their caregivers began to use the internet for healthcare information and content, developing thematic communities and support groups, e-commerce and communication between existing individuals (Eysenbach 2003).

As the focus of healthcare shifts to wellness and the individual becomes the center of information, it becomes important to have health technology where the focus is not just interconnectedness between the individual and the physician but also between the individual and the friend and family member. My second exploration focuses on addressing this shortcoming. A health technology is designed and evaluated for its effect on the interpersonal domain between an individual (person with diabetes) and a friend or family member whom the individual considers instrumental in providing support in managing his or her diabetes. The questions I seek to

address include: What happens when a friend or family member instantly knows about the blood glucose level of the person with diabetes? Are they even interested in it? Do they help him or her more once they know it?

3.5 Health Technology for Data Visualization

Effective visualization of complex data is required for it to be efficiently understood without any major cognitive or affective load. Here we need to focus on the complexity of the data as perceived by the individual and not by someone else such as a healthcare provider.

As the focus of healthcare shifts from disease cure to disease management and finally to wellness, it becomes more important to be able to quickly relate data from various physiological parameters over long periods and derive information from it.

Earlier for disease cure, it was sufficient for the physician to look at a series of physiological tests at an instant of time and prescribe medications accordingly. Here the physician needed to analyze and interpret information about one individual using one time set of measurements. He or she had the required training for interpreting the data presented in medical terminology and could interpret the technical data.

In disease management, this shifted to the need of being able to look at the patient history, probably compare it with other patients and then prescribe an effective treatment. The treatment changed as the condition of the patient changed over a time-period. This increased the cognitive load on the physician. The need to reduce this cognitive load led to development of visualization systems for health information such as patient records (Plaisant, Mushlin et al. 1998). Here the focus is on the physician who needs to view a large amount of data and importance is given to the layout and presentation of the data rather than abstraction of the data itself. From the physician side, this is understandable as he or she is used to having the data in a specific format and needs to interpret the data for diagnosis. Though the individual is also receiving some of this information, he or she is presented the information in the same format as the physician. It is often difficult for the individual to interpret this data.

However, as the focus of healthcare shifts to individual wellness, the individual becomes the center of information and thus the person who needs to understand and act on this information to maintain his or her health. A physician cannot be present with the individual 24/7 to help interpret data and provide information. It then becomes important to present health data to the individual in a way that it is useful for him or her. This requires reduction in the complexity of the data and abstraction of the useful information in a way that is easily understood. The data also needs to be presented to friends and family members that may be even less knowledgeable in the interpretation of the data than the individual himself.

For an individual, the ECG waveform is simply data (as compared to being information) that one is not capable of interpreting (most of the time). It is more useful for him or her to know if his or her ECG has any possible symptoms of cardiovascular diseases, the relation of his or her activity to the ECG, etc. He or she may acquire the knowledge over a time-period to interpret even the waveforms. It is less likely that his or her friends and family members will simultaneously acquire the knowledge. For them, it is more important to know how the individual is doing, how 'well' he or she is.

Another focus of my second exploration is based on data visualization for the individual and for her friend or family members. What are effective ways of presenting blood glucose levels to a person with diabetes so it can be easily interpreted by him or her? What are effective ways of presenting the same blood glucose level to a friend or family member of the individual so he or she knows how his or her loved one is doing? I used an ambient display to present the health information. The use of ambient media as a means to present information in our surrounding space in an abstract and un-monopolizing way is not new and has been used for connecting people (Holmquist, Wigstrom et al. 1998). However, its use to display health information as in my second exploration is novel.

4 Exploration A: Wireless Bandage-Sized Sensors

4.1 Introduction

My first exploration focused on using technology to make the individual and the environment more aware of an individual's physiological state. Information about the state of an individual needs to be spatially distributed and temporally integrated for healthcare to be effective. The intent is for healthcare to be personalized and yet communal.

I explored the concept of a distributed sensor network of wireless bandage-sized sensors for wearable health applications. As a building block for the network, I made a wireless sensor for measuring and communicating ECG signals. However innovative it is as a cheap, 3-lead ECG sensor, it gives an example of using wireless technology for creating a community of small-sized health sensors suitable for long-term use. It breaks the barrier of having wired sensors measuring in isolation.

4.2 System Description

Functional	It measured ECG signals and transmitted them wirelessly to a base station where the signals could be stored and analyzed
Physical	2 inch X 1.5-inch board. The interface to the human body was through 3 electrodes
Technical	It used a custom-built 2-stage analog amplification and filter circuit to measure ECG signals using INA321. The signals were then digitized and then transmitted to a base station using a 2.4 GHz Nordic nRF1 transceiver. The sensor operated at 3V using CR1220 batteries.
Economic	ECG sensor board at \$48 per piece (It is to be noted that half the cost is of fabrication)

4.3 System Specification

A design goal for developing a bandage-sized sensor was to be able to have function-specific sensors that are small, low cost, low powered, wireless and easy to use: like a bandage. The idea was to develop 'plug and play' sensors that an individual would need to just stick on themselves and the sensors would automatically take care of the rest. This would improve health technology along the cognitive dimension with respect to access of information and improve health technology along the affective domain by improvement in comfort.

In the long term, the vision was to make them building blocks for self-organizing health networks where the health information can be spatially distributed and temporally integrated. Spatial distribution would ensure that health at multiple levels of an individual, a family or a community could be measured and observed instantaneously while at the same time allowing the environment to be more effective in adapting itself to the changing health of the person. Temporal integration would ensure adaptation not only across space but also across time through long-term analysis of data and prediction. The sensor could connect itself to the healthcare provider, with the individual's permission, providing them with ECG data for the past week and the physician could change the behavior of the sensor to suit individual's personal needs.

Towards that end it was important that the communication be bi-directional and multiple sensors be able to coexist, thus improving health technology along the interpersonal dimension.

4.3.1 Functional Specification

Functionally, the specifications could be reduced to four sub-functions: sensing, processing, communication and power. Figure 2 shows the functional block diagram of the sensor.

The sensing requirements needed a sampling rate of at least 500 Hz and a signal resolution of 8 to 12 bits for adequate accuracy of the ECG signal. Thus the bandwidth of the sensors needed to be at least 1 KHz. An ECG Signal consists of a small signal voltage (5 to 10 mV) accompanied by a large ac common-mode component (up to 1.5V) and a large dc variable component (300 mV). Thus, a Common Mode Rejection Ratio (CMRR) of at least 80 dB was required. The sensed signal needed to be amplified differentially, filtered and matched to the range of the Analog to Digital Converter (ADC).

Processing of the signal involved its digitization and encoding for transmission. Communication involved wireless transmission to the base station that can use the signal for storage and analysis. The communication range needed to be of few meters or less as the sensor was primarily meant to send data to a base station that would be present with the individual.

Since the sensor was wireless, a battery source was needed for power that could provide power at least for a day. The sensor also needed to be easily reprogrammable.

4.3.2 Mechanical Specification

The board layout needed to ensure that the four different kinds of signals-power, analog, digital and RF, do not cause interference with each other and there were adequate mechanisms to limit noise interference. Noise from the digital circuitry (microcontroller within nRFE1) varies from being high frequency noise on the scale of the clock frequency to low

frequency noise of the order of milliseconds and tends to be of high amplitude. Electromagnetic noise interference especially with onboard RF circuitry can easily propagate through the board, especially through open-ended conductors and PCB tracks. Power supply noise could be due to AC line noise or long-term voltage variations.

4.4 Design

Based on the above specifications, a sensor was designed that used a custom-built two stage analog amplification and filter circuit to measure ECG signals using a Texas instruments INA321 (TI 2004) instrumentation amplifier. The amplified signal was digitized and transmitted to a base station using an ultra low-power transceiver by Nordic VLSI (nRF24E1) (Nordic 2004). The chip featured an integrated 2.4 GHz transceiver with an 8051-based microcontroller and a 9-channel 12-bit ADC. Power was supplied through a 3V Lithium cell. Detailed schematics, bill of materials and layouts have been provided in the Appendix A.

4.4.1 High Level Component Selection

The above components were selected based on the functional and usability specifications for the sensor. The selection of the components can be divided according to their function: sensing, processing, transmission and power. An attempt was made to use integrated solutions that combined two or more functions on a single chip. This reduced bill of materials, conserved board space while at the same time reduced system development time. In the next few paragraphs, we provide a rationale for the selection of the components.

Sensing & Signal Measurement

My initial thought was to use custom chips specialized for medical applications. The high cost of chips specialized for ECG measurement (read Federal Drug Authority approvals) that offered integrated analog measurement circuitry with ADC ruled out its use. Most of these chipsets were designed for use in hospital equipment, and required dual power supply and operated from +15V. As discussed later in the selection on power, this would have significantly increased the power consumption of the sensor.

As discussed in the section on design of power circuitry, it was decided to use a single power source. For precise measurement of differential signals with a large common mode, instrumentation amplifiers are recommended (Horowitz and Hill 1989). Thus, the selection of the operational amplifiers was reduced to single supply instrumentation amplifiers that offered a high CMRR (common mode rejection ratio), were low cost, low powered and low noise. A low operating voltage translated to a requirement for the amplifier to provide rail-to-rail amplification. It was also important that the shutdown current of the amplifier be low to maximize battery life. Based on these considerations Texas instruments INA321 was selected.

The amplifier is recommended for use as a physiological amplifier and has been used previously at the MIT Media Lab in Every Sign of Life Board for measurement of ECG Signals (Gerasimov 2003).

An important consideration in the performance of the amplifier is noise. For high source impedances as is the case in the case of the ECG electrodes, the transistor current noise dominates, it is important for the amplifier to have low current noise (Horowitz and Hill 1989). The current noise of the INA321 is $3\text{fA}/\sqrt{\text{Hz}}$ making it a good choice.

Processing

The computation requirements were minimal as it was decided early in the design that most of the signal processing would be at the base station. Thus 8 bit microcontrollers were chosen over other processing options like digital signal processors (DSPs), field programmable gate arrays (FPGAs) as microcontrollers were easy to program, cost effective and available in ultra low power consumption.

The important features in the choice of the microcontrollers were integration of multiple functions, operating voltage and support for low power sleep modes. Sensing for real world applications, especially ECG signals rarely require the measurement frequency to be above a few KHz. However, most of the current chips have a clock frequency of at least a few MHz. This made it important that the microcontroller support ultra low power sleep modes as the chip would spend a majority of its time in this mode. The choice was quickly reduced to the Nordic (Nordic 2004) and Xemics (Xemics 2004) chipsets based on the design goal of having maximum system integration. Xemics offered an internal ROM, additional functions like digital to analog converter (DAC) and capacitive coupling circuits that would have been useful for designing other types of sensors. However, it did not feature an integrated RF communication unit. Nordic featured an integrated RF communication with 8051-based microcontroller but required an additional EEPROM for programming and did not have a digital to analog converter (DAC) or other functions provided by Xemics. Nordic emerged as the choice due to compatibility with other groups at the MIT Media Lab which were using Nordic for the design of their sensors. Also for mass production, an EEPROM was not required as the program could be flash loaded into the ROM of the chipset itself. An external AA320 EEPROM was used for programming the Nordic nRF24E1 transceiver.

Communication

The communication mode was chosen to be RF over optical or IR due to line of sight limitations in optical and IR. There has been rapid development in the integration of RF communication with existing electronic devices. Thus RF communication provided a way of future integration of the developed sensors with commercial devices

The frequency of RF communication was chosen to be 2.4GHz based on consideration of antenna size and the possibility of integration with other networks. For optimal functioning, the antenna size needs be at least $\lambda/4$, λ being the wavelength of the carrier frequency. 2.4GHz is also used for 802.11 networks and Bluetooth. Due to the widespread use of 2.4GHz communication, costs for development of 2.4GHz systems are low and antennas are easily available commercially. Higher frequencies, though attractive from the point of antenna size were not selected due to development costs, requirement of specialized equipment for its development and lack of easily available parts. The boards are also difficult to design at higher frequencies as the components show increased non-ideal behavior and it is easier for the RF waves to propagate through the board and contaminate the analog signals.

Among the available 2.4GHz solutions, the major choice was between using Bluetooth vs a custom protocol. Bluetooth is an emerging standard that provides specifications for short-range radio links (Bluetooth, 2004). It was attractive in terms of providing a ready to use network protocol for power management, organization of the network and integration with commercially available Bluetooth devices. However, at the time of development of the sensor, lack of a low power integrated solution for Bluetooth prevented its use. Transceivers were preferred over transmitters to allow for bi-directional communication and thus the possibility of remote control of the sensor. This is important for creating self-organizing sensor network and reducing work in the design of base stations. Based on the design goal of maximum integration and other reasons mentioned in the previous section, Nordic nRF24E1 was used for development. The Nordic transceiver was favored over other transceivers as it supported low power communication protocols, required minimum external components and allowed for multiple channels of communication from the same sensor. A review of some of the existing transceivers is available in (M. Laibowitz 2004). Printed antennas were also fabricated but were not used in the development of the first prototype. The selection of the rest of the components was based on guidelines provided by Nordic.

Power

The system was powered by a 3 V lithium 1220 cell with power being directly supplied to the different sub systems without any additional voltage regulators. A 3 V operating voltage was chosen to eliminate the need for external voltage regulators. A lower operating voltage meant lower power consumption at the same current drain thus extending battery life. However the use of a lower operating voltage power source makes the system less immune to environment noise and makes measurement of weak electrical signals like ECG difficult as there is less room for amplification. Lower operating voltages of 1.5 V were also tried but the differential gain on the ECG signal was not high enough to allow for a good measurement. Another possible option was to use a step up voltage converter but that would have added component cost, increased board size and added to system noise.

Lithium cells provide a flat drain curve as compared to other cells that have a sloping drain curve. A sloping energy drain curve limits the percentage of stored energy that is available for the sensor as the cell voltage quickly falls before the operating voltage and thus is not good for applications where continuous operation is required.

Mechanical Design

The sensor was manufactured on a standard Fr-4 material and 1 oz copper plate. This was the available material for manufacturing of the printed circuit board. The connector used for interfacing the electrodes was a standard 8-pin 1.25 mm molex connector.

4.4.2 Low Level Design

With the selection of the major components, the next step was to complete the design of individual functional circuits and their interface.

Electronic Design

The ECG measurement circuit is a modification of an ECG amplifier from INA321 specifications. The schematic of the ECG circuit is shown in figure 4-1. The ECG signal as measured from the electrodes is differential floating with a common mode voltage set by the reference voltage of 1.2V using ECG_R2 and ECG_R3. The ECG signal is amplified and filtered in two stages.

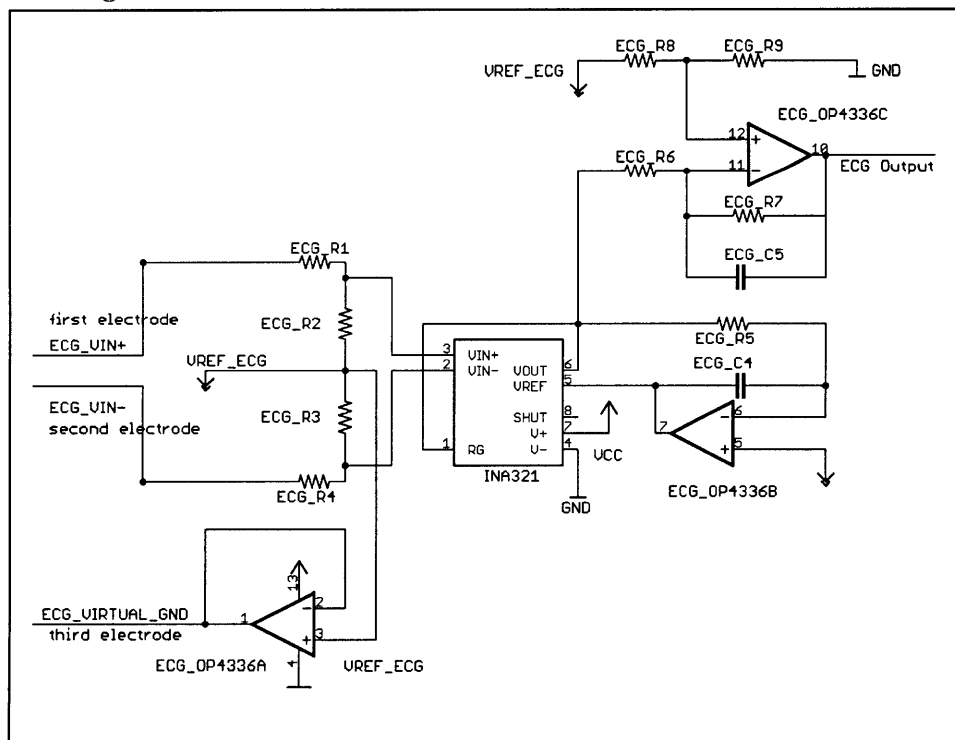


Figure 4-1 Schematics of the ECG Measurement Circuit

The first stage involves using an instrumentation amplifier INA321 to amplify the differential signal present between the two electrodes and rejection of the common mode noise using the instrumentation amplifier. The gain is set to 5 to allow for large DC offsets. Dynamic correction of the DC offset with respect to the reference voltage VREF_ECG is done through a high pass filter using the second operational amplifier ECG_OPA4336B with ECG_R5 and ECG_C4.

The first operational amplifier ECG_OPA433A provides an active ground to minimize common-mode noise through the third electrode and limits the return current to the body in case of a ground fault. The third operational amplifier ECG_OPA4336C provides further amplification of the differential signal with a low pass filter using ECG_R7 and ECG_5 to remove the high frequency noise. Here high frequency noise is an important consideration due to the presence of RF circuitry on the same board. The gain is set to 45 to match the range of the ADC.

The interfacing between the ECG signal measurement circuitry and nRF24E1 was straightforward. The amplifier and filtered ECG signal and the voltage reference are connected to the analog input pin AN4 and ADC voltage reference pin AREF of the Nordic Chip. Low pass filters (C16, C19, R3 and C21, C23, R4) are used to remove any high frequency noise. Figure 4-2 gives the schematic of the interface between the ECG Circuitry and nRF24E1.

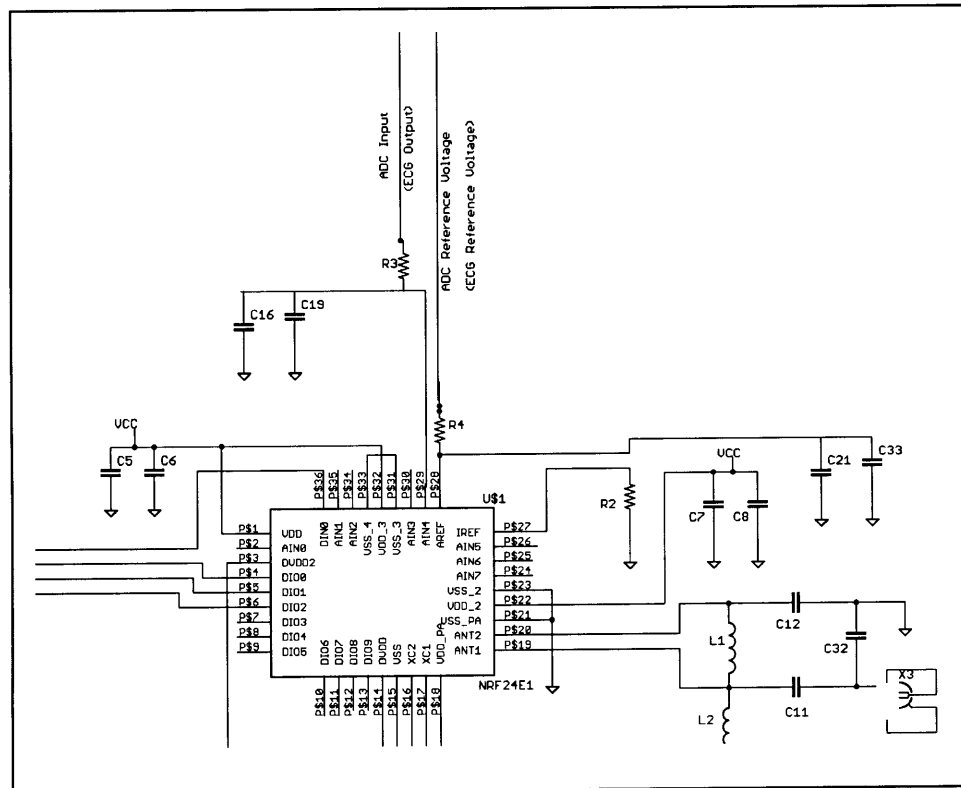


Figure 4-2 Schematics of the ECG-nRF24E1 interface

Power circuitry consisted of the power source, the voltage reference and the decoupling capacitor network. A 1.2V voltage reference was used (LM385) for providing a bias to the ECG signals. At GHz frequencies, the selection of the discrete components like resistors and capacitors becomes important as these components start to show non-ideal behavior (Horowitz and Hill 1989). The decoupling capacitor network designed was based on ground rules provided by Nordic documents and other sources on design of high frequency circuits (Nordic 2004). The decoupling capacitor network is given in Table 4-2.

Capacitor Value	Footprint	Description	Number of Capacitors
22pF	0603	Capacitor Ceramic NPO 50V	1
1nF	0603	Capacitor Ceramic X7R 50V	5
10nF	0603	Capacitor Ceramic X7R 50V	5
22nF	0603	Capacitor Ceramic X7R 50V	1
33nF	0603	Capacitor Ceramic X7R 50V	1
100nF	0603	Capacitor Ceramic X7R 50V	4
1uF	3216	Capacitor Tantalum 20V	1
4.7uF	3216	Capacitor Tantalum 20V	1
10uF	3216	Capacitor Tantalum 20V	1

Table 4-2 The Decoupling Capacitor Network for ECG Sensor

The package of the capacitors was chosen to be NPO package. Where the NPO package was not available, X7R and for higher capacitances tantalum was selected. The capacitance value of the needed capacitors was based on calculations of their mounted resonant frequency which determines the frequency range over which it will be effective as a decoupling capacitor (Xilinx 2004). The choice of the package was based on the need to minimize parasitic inductance thus the smallest possible package that could still be hand soldered was selected. The package type was 0603 type as they provide the lowest parasitic inductance with an acceptable temperature characteristic (Xilinx 2004). A larger package (3216) was selected for higher capacitance values where the smaller package was not available. The mounted resonant frequency of each of the capacitors was selected to ensure minimum noise. The number of capacitors was determined based on the rule that a capacitor has to be within $\lambda/40$ of the distance from the power pin that it is decoupling, λ being the wavelength of the frequency being decoupled. Based on this the

number of capacitors required for each pin was determined. For example, a decoupling capacitor of 4.7 uF needs to be within 123 inches (corresponding to a resonant frequency of 1.56 MHz) of the decoupling pin (Xilinx 2004). Thus it could be placed anywhere on the board and it is sufficient to have one such capacitor. Figure 4-3 provides the different capacitors present in the decoupling network.

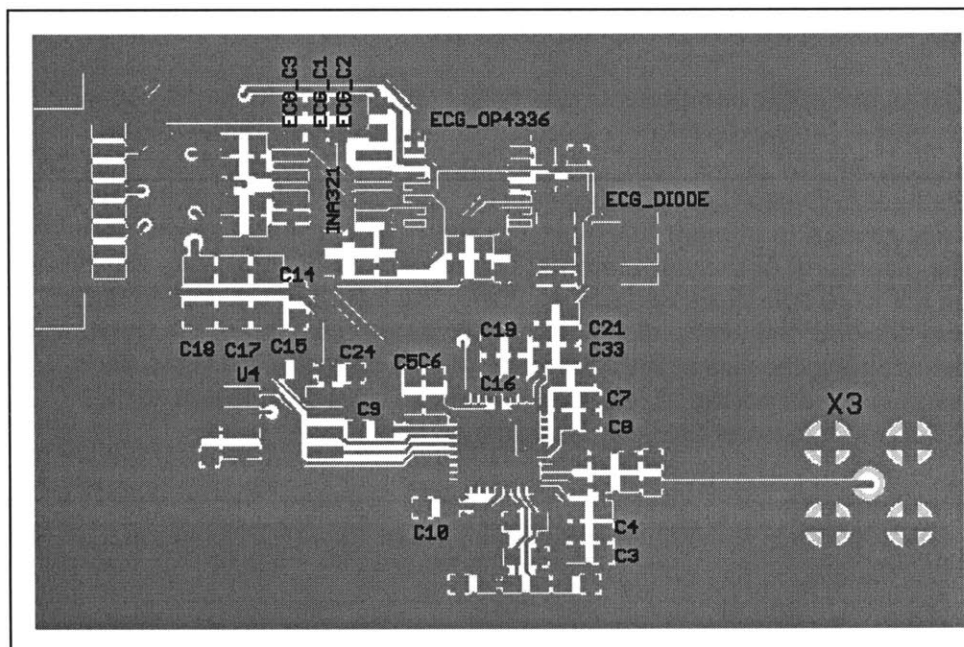


Figure 4-3 Decoupling Capacitor Network for ECG Sensor (board size 2 inch X 1.5 inch)

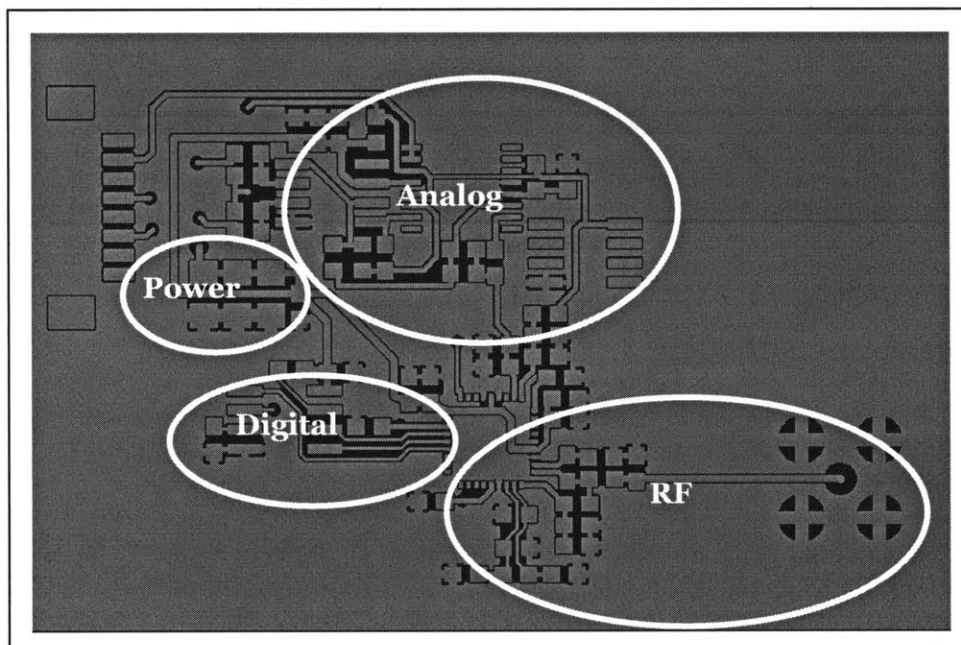
Mechanical Design

PCB design is very important for the correct functioning of the sensor and effective separation was required between the analog, digital, RF and power circuitry to prevent noise.

Best practices were adopted as recommended by various sources (Xilinx 2004), (Nordic 2004) for the determining of the layout and mounting of the components and PCB tracks. There was a tradeoff between designing a PCB for maximum noise resistance and minimizing cost of fabrication. Important characteristics in a PCB design are the thickness of the board, the layout of the components and PCB traces, size of the different features on the board (vias, pads, traces) and provision of ground planes. The guiding principle was to minimize inductance along the current paths to provide effective decoupling and minimize noise. The sensor was manufactured as a two-layered board of 0.062 inches thickness with the material type FR-4 and 1 oz copper plate. A two-layered board as compared to a multi-layered board was chosen based on cost considerations. A better solution would have been to have separate power planes for RF, analog and digital components and a ground plane.

Fabrication of a multi-layered board would have significantly increased the costs so it was decided to go for a two-layered board. Here importance was given to having a separate ground plane apart from the component layer. This allows for higher frequency decoupling. The topside of the board was used for the components and the bottom was made the ground plane with space for the battery. Board thickness was kept to a minimum to minimize the spacing between the power tracks and the ground planes this reducing the size of the current loops.

The layout of the components was based on modifications of layouts suggested by Nordic (Nordic 2004) and used to separate the digital, analog, RF and power components of the circuit. It is important that the distance between these components be maximized and separated by a large ground to prevent interference. Figure 4-4 provides an overview of the placement of the components. The placement of capacitors was based on the $\lambda/40$ rule discussed earlier. Once the layout of the components was decided, the next phase was to determine the layout of the traces and determining the size of the different features on the board (vias, pads, traces, unused portions). Figure 4-5 gives a visual description of the different features of the board mentioned above.



**Figure 4-4 Layout of the Components on the ECG Sensor Board
Sensor (board size 2 inch X 1.5 inch)**

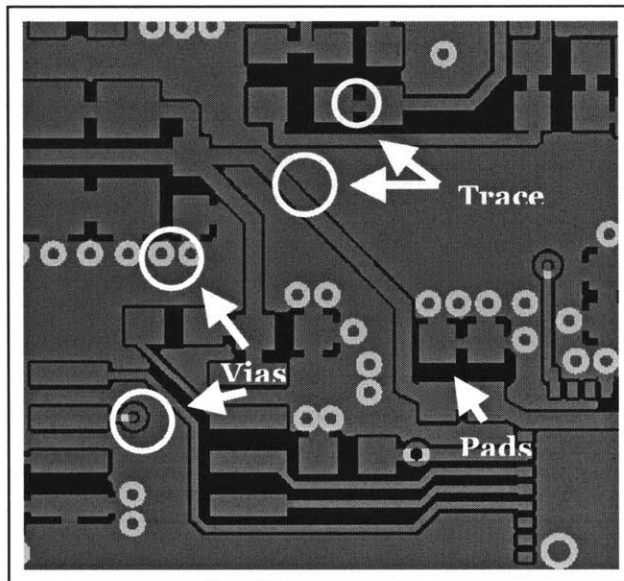


Figure 4-5 Different Features of the ECG Sensor (board size 2 inch X 1.5 inch)

Figures 4-6 and 4-7 provide the PCB layout of the top and the bottom layers. A complete PCB layout is present in Appendix B. Due to manufacturing constraints, the minimum distance between two features was 0.006 inches and the minimum feature size was 0.006 inches. The connecting traces were kept to a minimum with the vias being placed close to the component pads to minimize parasitic inductance. Although optimum, it was not possible to have vias collocated with the pads due to manufacturing constraints imposed by the PCB manufacturer.

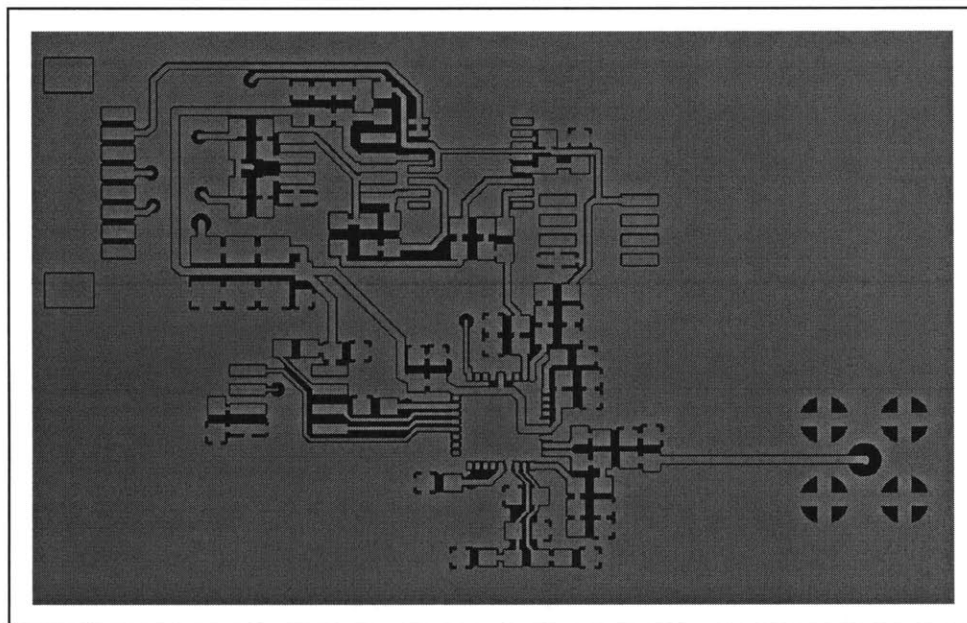


Figure 4-6 Top Layer PCB Layout of the ECG Sensor (board size 2 inch x 1.5 inch)

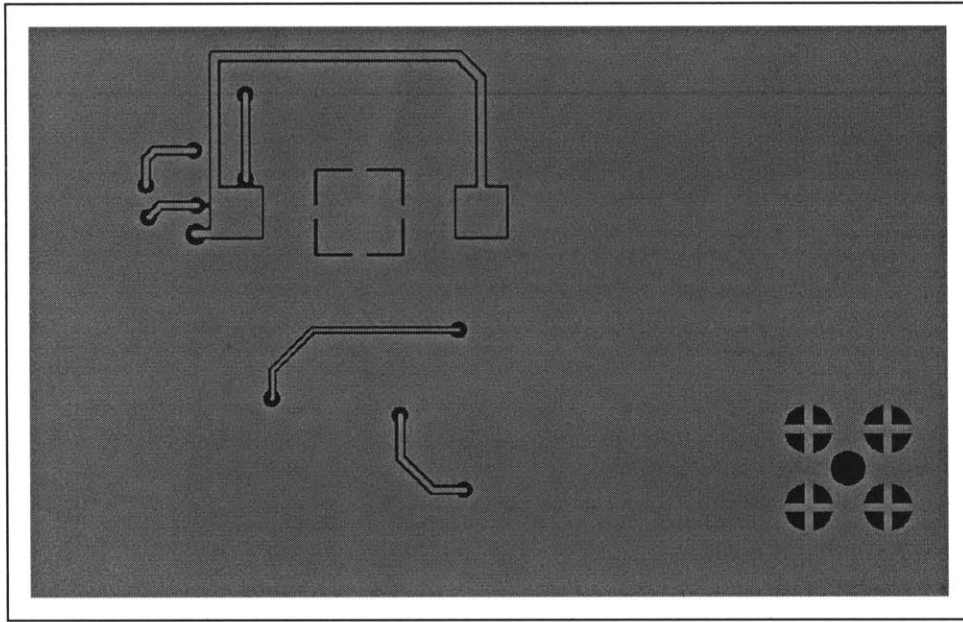


Figure 4-7 Bottom Layer PCB Layout of the ECG Sensor (board size 2 inch x 1.5 inch)

The ratio of the number of vias to the pads was kept one to one and wherever permitted by the feature distance restrictions, multiple vias were provided. In RF design it is strongly recommended that the vias not be shared between 2 pads. Vias were provided adjacent to the power trace to minimize inductance of the current paths. The inductance of a current path is proportional to the area of the loop it traverses. Figures 4-8 and 4-9 show the layout of the vias on the top and bottom layers of the PCB. Figure 4-8 (top) and Figure 4-9 (bottom) Placement of Vias on Top and Bottom Layer of ECG Sensor.

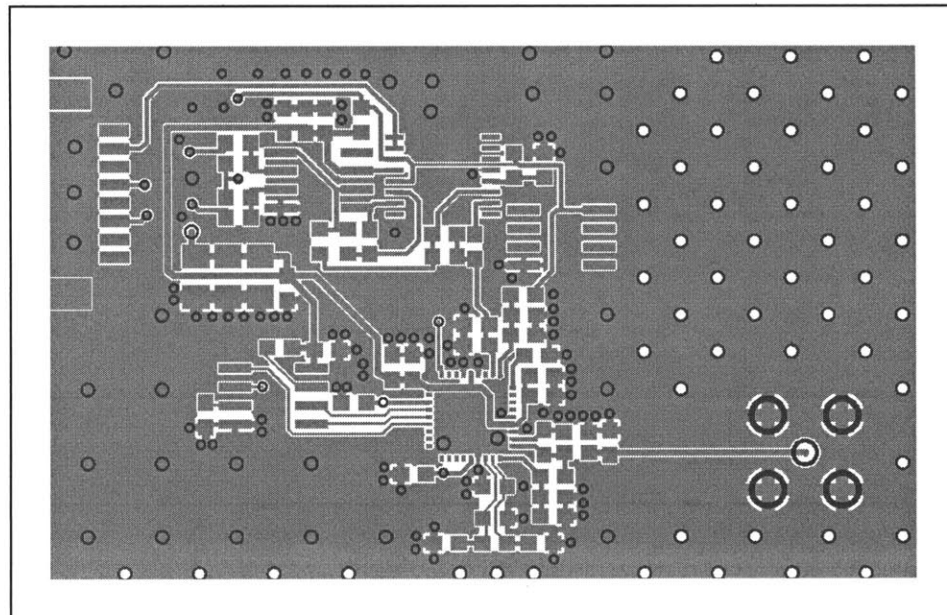


Figure 4-8 Placement of Vias on the Top Layer of the ECG Sensor Board (board size 2 inch X 1.5 inch)

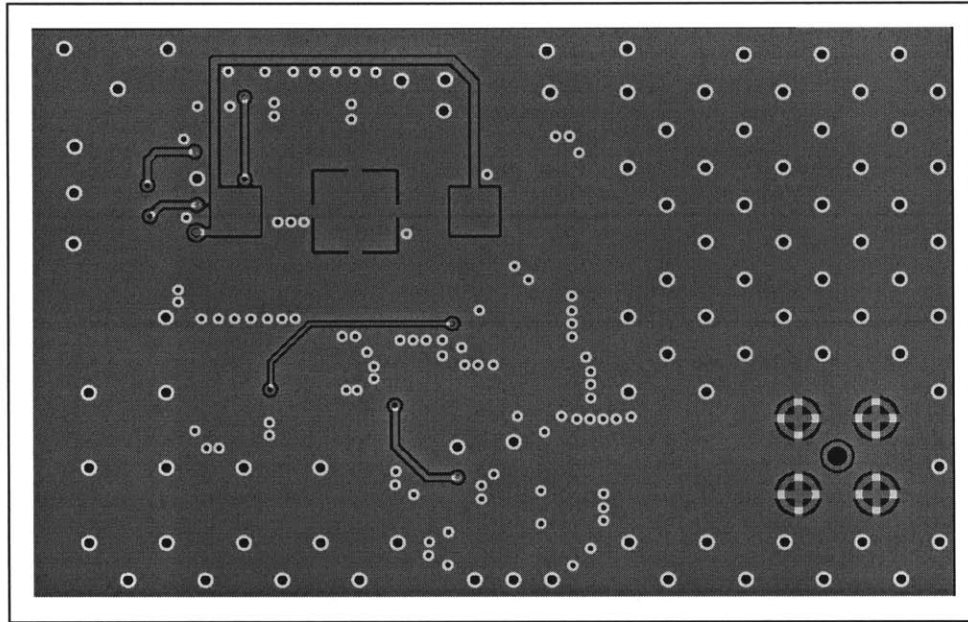


Figure 4-9 Placement of Vias on the Bottom Layer of the ECG Sensor Board (board size 2 inch X 1.5 inch)

The trace width of the power signals was maximized to increase the sandwich capacitance between the power trace and the underlying ground plane. This also minimizes inductance. Star routing was adopted to separate power for analog, digital and RF circuitry.

Software

The embedded software in the microcontroller controlled the data processing and communication. It initialized the ADC and the transmitter and entered into an infinite loop, continuously reading the ADC and transmitting the read data to the base station. The software was designed in collaboration with Emmanuel Munguia Tapia at the MIT Media Lab.

4.5 Fabrication

Version 1 as generally true for most circuits was using a breadboard in conjunction with the Nordic development kit. Version 2 involved fabricating the circuit board and surface mounting the components. Figure 4-10 shows a picture of the actual fabricated board.

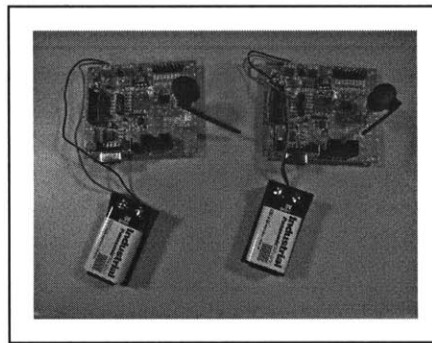
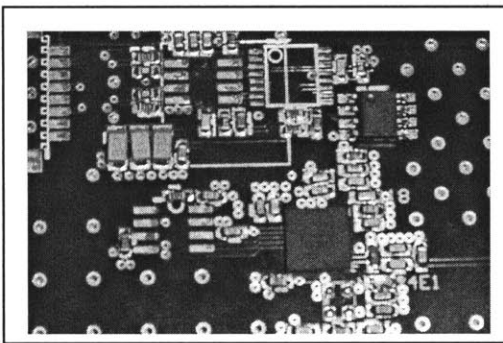
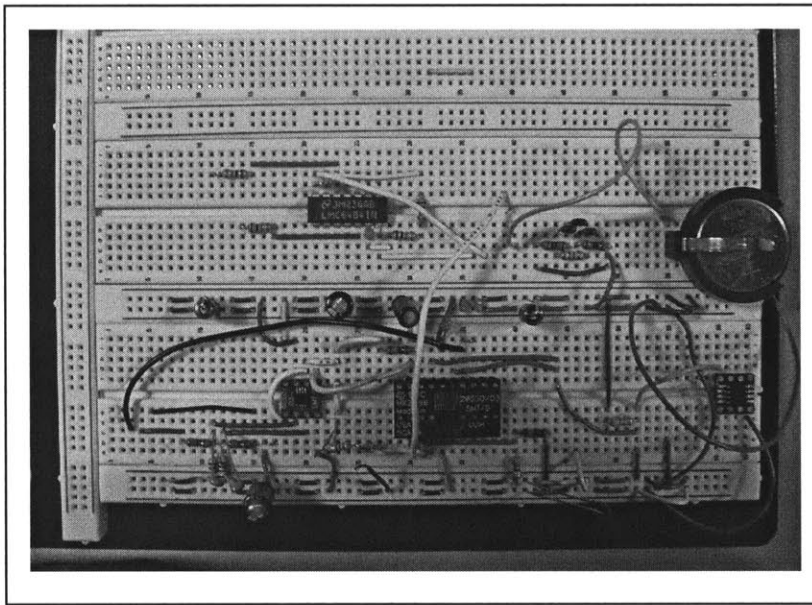


Figure 4-10 Clockwise From top: the breadboard version of the ECG Sensor, The Nordic Development Kit and the Fabricated Board (Actual size shown: 2 inch X 1.5 inch)

Table 4-3 provides an overview of the different resources used in the testing and fabrication of the PCB.

Circuit Design and Layout	Eagle Layout Editor 4.11r2
Firmware	Keil Software C51 μ Vision2 IDE development tools
Assembly & Soldering	Hand soldering and using a Proctor Silex toaster oven !!
Signal Testing	Tektronix TDS3052 2-Channel Digital Oscilloscope
RF Testing	Agilent E4404B 100 Hz – 6.7GHz Network Analyzer

Table 4-3 Hardware and Software Resources Used for Testing and Fabrication of ECG Sensor

4.6 Results

Figures 4-13 provide the ECG waveform from the sensor board as observed on the oscilloscope. The board had limitations when it came to noise interferences and at times would lose the ECG signal due to background noise. A possible reason could be the power harmonics. A separate filter to remove the power harmonics was not included thus any differential signal within 0.01 Hz to 500 Hz was amplified including the power harmonics and background noise. A large part of the power harmonics is not amplified as it is present as a common mode signal but there may be small differential components of the power harmonics that can get amplified.

It was found that performance was improved if 100pF capacitors were added in parallel with ECG_R2 and ECGR_3. They acted as low pass filters and removed the high frequency component. This also removed the need for components R3, R4, C16, C19, C21, C33 that were present at the interface of the ECG sensor and nRF24E1 (the analog input pin AN4 and ADC voltage reference pin AREF) to filter high frequency noise. The results in Figure 4-13 are with these modifications.

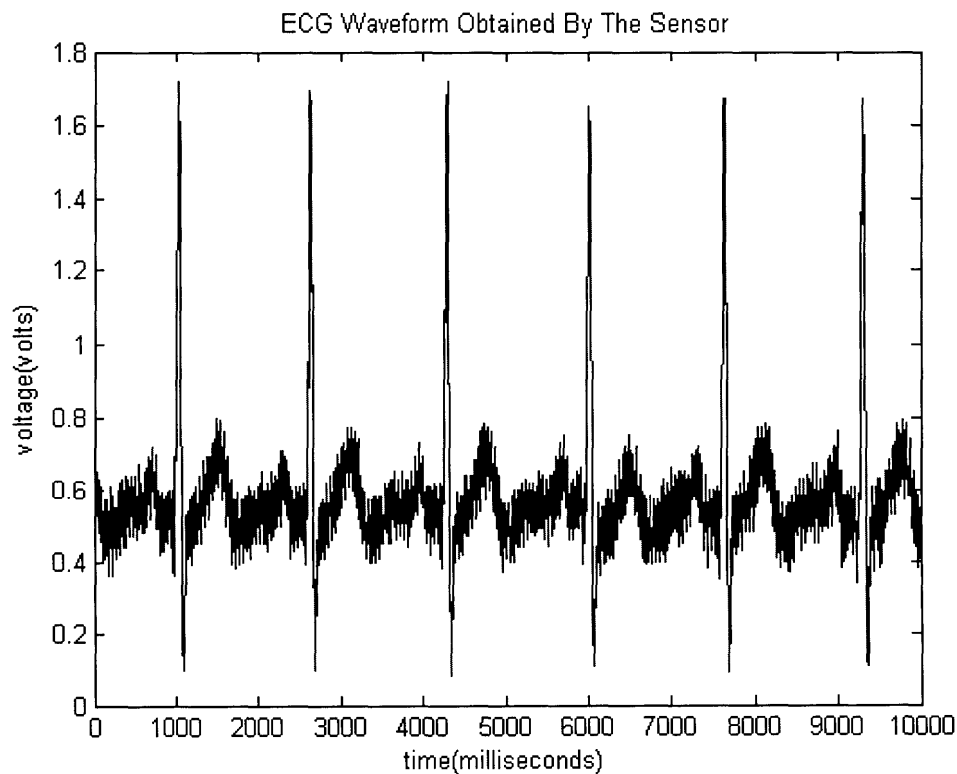


Figure 4-13 ECG Waveform Obtained from the ECG Sensor

4.7 Conclusion

A wireless bandage-sized 3-lead ECG sensor was built to serve as a building block for a network of health sensors-personal and interpersonal. The sensor was designed with the aim of improving the interaction with an individual along the affective, cognitive and inter-personal domains. It was a proof of concept to show that the existing technological components in the area of sensing and communication are sufficient to create cheap and small-sized wireless wearable sensors.

5 Exploration B: Effect of Ambient Displays on Social Support and Diabetes Management

5.1 Introduction

My second exploration focused on using technology to make the environment itself become the medium of expression of the individual's physiological state. The environment then becomes a medium of communication of health information to other individuals. Health information dispersed into the environment: individualistic information in a collective environment.

I explored the effect of using ambient displays for visualization and feedback of health information. Towards the goal, I designed and evaluated a computer-based ambient blood glucose level visualization and feedback device and evaluated its effect on diabetes self-care. The device displayed the blood glucose level of an individual as a color. It gives an example of the power of a color as a medium of expression for healthcare information especially due to its affective qualities. It encourages machines to speak our 'language' rather than only numbers and thus reduce complexity for the individual in understanding them.

5.2 Methodological Framework

5.2.1 Study Objective

The study objective was to evaluate the use of health technology by an individual along the affective, cognitive and interpersonal domains. Clinically, the study aimed to evaluate the efficacy and usability of a computer-based ambient glucose visualization and feedback tool in supporting diabetes self-management in adults with type 1 or type 2 diabetes. The intervention was through the Health-Zero ambient orb provided to the participant and optionally to a close friend or family member of the study participant. The ambient display displayed blood glucose readings as a color whenever the blood glucose level was measured with a blood glucose monitor. The initial idea of the use of an ambient device for data visualization and social support was through conversations with Brent Lowenson of Kaiser Permanente. The study was developed and implemented in close collaboration with Dr. Katie Weinger at the Joslin Diabetes Center.

Primary Hypothesis:

Participants that use the Health-Zero ambient orb (personal Health-Zero orb) will demonstrate improved self-care behavior as compared to their baseline self-care behavior.

Participants that use the Health-Zero ambient orb and whose friend or family member have a Health-Zero ambient orb (friend or family Health-Zero orb) will have improved self-care behavior in comparison to the participant's baseline self-care when he or she or the friend or family member did not have any such feedback tool present.

The first hypothesis focuses on improvement in participants' cognitive domain in diabetes care by providing a visualization tool while the second hypothesis focuses additionally on improvement in the interpersonal domain by creating a communication channel between the participants and their friend or family member.

5.2.2 Apparatus

Motivation for the System

The current methods for monitoring blood glucose levels are limited, providing a numerical value and graphs to people with diabetes and occasionally to their healthcare providers. The current method of visualization of blood glucose levels uses graphs to represent the blood glucose levels. There is no automatic mechanism for the communication of blood glucose levels to the friends or family members of the people with diabetes even though friend and family members play an important role in diabetes self-care of the individual (Skinner, John et al. 2000; Toljamo and Hentinen 2001). Currently this happens only through personal communication between the person with diabetes and the friend or family member. Furthermore, the family members do not have the same level of knowledge as the diabetic for co-relating the blood glucose readings with the diabetic's health.

For the purpose of this study, a computer-based ambient visualization and feedback tool was designed that allowed people with diabetes to measure their blood glucose level through a glucose monitor and display it as a color on a orb. The orb could be with the diabetic and optionally also with a friend or family member.

System Description

The system (figure 5-1) enabled a glucose meter (LifeScan One Touch Ultra) to wirelessly connect to an ambient orb through the study participant's home computer. It consisted of a glucose meter, Device 2 (Bluetooth Transmitter) that attached to the glucose meter, Device 1 (Bluetooth Receiver) that attached to the home computer, the Health-Zero ambient orb (Ambient Devices Stock Orb) and client software on the home computer. Johnson and Johnson provided the One Touch Ultra Glucose Meters and the test strips for the study. Ambient Devices provided their Ambient Stock Orb for use as Health-Zero orbs and the Ambient Network was used to control the Health-Zero Orbs.

The client software periodically (every twenty minutes) established a Bluetooth wireless connection between the glucose meter and the home computer to upload the most recent blood glucose value to the home computer. It then converted the blood glucose value to a color value. The color was determined using a scalar measure developed in consultation with Dr. Katie Weinger at the Joslin Diabetes Center and based on guidelines provided by the Joslin Diabetes Center (Joslin 2004). This color value was then transmitted to the orb that displayed this specific color. The color on the participant's orb was retained until a new blood glucose reading was obtained. If the last reading of the participant was at least six hours old, the orb also blinked at the same time. The technical specifications of the system have been provided in Appendix C.

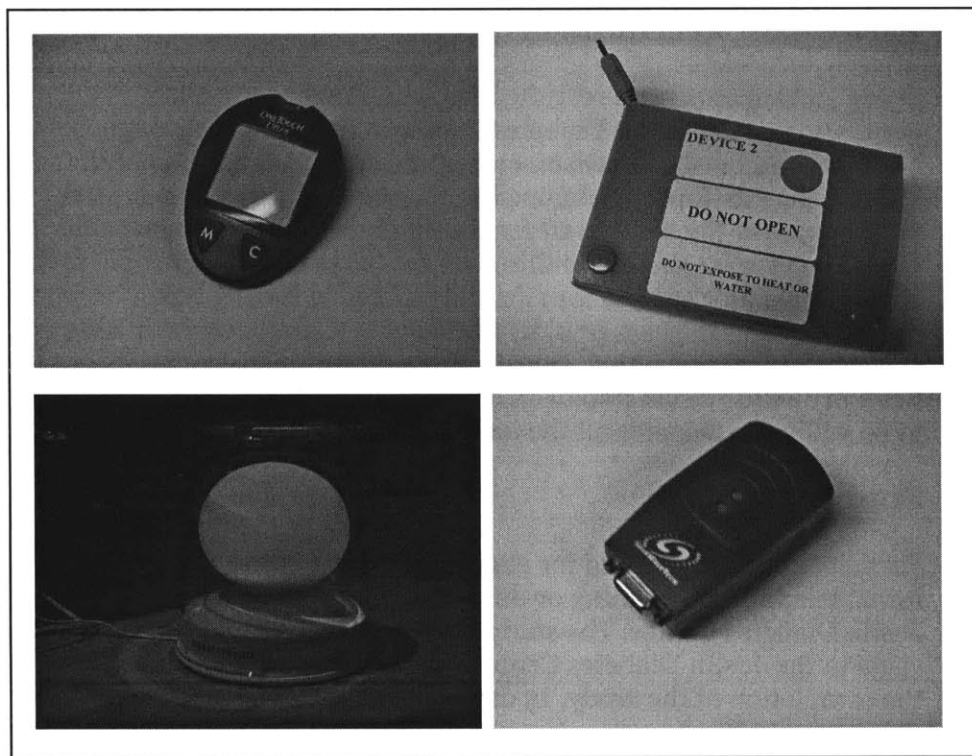


Figure 5-1 The Health-Zero Ambient Display System (clockwise from top left: glucose meter, Device 2, Device 1 and Health-Zero Ambient Orb)

The system aimed to improve the cognitive domain of people with diabetes by being a visualization tool for them and reminding them of their blood glucose level. It also created a new communication channel between people with diabetes and their friend or family members. This provided a constant feedback mechanism for knowing the health of people with diabetes through their blood glucose levels and improved the interpersonal domain of individuals with diabetes.

The use of the system involved installation of the client software on the participant's home computer and use of the provided glucose meter to check blood glucose level. Device 2 was to be attached to the

glucose meter and Device 1 was to be attached to the serial port of the home computer. The Health-Zero orb was to be placed at a location where it is easily observable by the participants or the friend or family member of the participants, depending on its use. For the system to work, the glucose meter needed to be connected to Device 2 by a cable and be in proximity (within 30 feet) of the computer. Constant internet connectivity was required and the Health-Zero orb needed to be in range of the ambient device network. During the study, the participants were instructed to keep the glucose meter preferably in the same room as the home computer. Appendix H provides the installation and usage instructions provided to the participants.

5.2.3 Experimental Design

Participant Recruitment

Study participants were recruited from mailings to the clinic population of the Joslin Diabetes Center in Boston and through brochures and wall advertisements at the Joslin Diabetes Center. Written permission was obtained to release the names of potential participants to the study staff for the mailings. A recruitment table was also set up at the Joslin Clinic for two days to attract people to the study. The major criteria for eligibility included having type 1 or type 2 diabetes, being 18 years or older and having a computer with a high-speed internet connection. It was necessary for the participants not to have any major visual impairment or color blindness. Participants had to be willing to perform all the tasks required in the study.

Study Procedure

Participants were checked for eligibility criteria either through an initial telephonic screening or during their first study visit at the Joslin Diabetes Center. The study lasted for 15 days and involved two visits to the Joslin Diabetes Center: Visit 1 at baseline and Visit 2 on the completion of the study, 15 days after Visit 1.

Visit 1

Visit 1 was a screening and baseline assessment visit for the participants. They received an explanation of the informed consent form that included description of the study objectives, study procedures and study compensation. They were allowed to ask questions about the study and the informed consent form. It was emphasized that the study was an important part of a graduate thesis at the MIT Media Lab and they should be willing to complete the study.

If they agreed to participate in the study, they were asked to sign the informed consent form and a HIPPA addendum that allowed the study staff to access their medical record for obtaining their HBA_{1c} value. A copy of the consent form and the HIPPA addendum was

provided to the participant. HBA1c is a test that indicates the average blood glucose control of an individual with diabetes over the past 2-3 months. The participants were checked for the eligibility criteria. If they were found eligible, they completed the baseline assessment questionnaire (Appendix G1) used for obtaining demographic information together with questionnaire related to their management of diabetes and social support (Appendix G2 and Appendix G3). Participants were then given a description of the system and instructions for its use and installation procedures (Appendix H). The instructions on the use of the device included guidelines for the interpretation of the blood glucose levels based on the color displayed on the Health-Zero orb.

Participants were informed that they needed to use the system for about 15 days and had to measure their blood sugar at least four times a day. They had to bring back all the equipment provided to them on their second study visit to the Joslin Diabetes Center. They were also asked if they could be contacted for checking the status of the system. It was emphasized to them that the color on the Health-Zero orb was to be used only as a reminder of their blood glucose level and they should not make any changes to the steps they take for measuring their blood glucose level or to their normal routine for managing their diabetes based on the color of the Health-Zero orb.

The participants were asked about their willingness to give a second Health-Zero orb to a friend or family member with whom they could share their blood glucose level. If they agreed, a second Health-Zero orb for use by the friend or family member was given to the participant. They were also provided with an instruction packet for their friend or family member that explained the use of the device and guidelines on the interpretation of the color displayed on their device (Appendix I)

During the Study Period (about 15 days)

After Visit 1, the participants installed the Health-Zero system on their home computer. If the participants had any trouble installing the program, they could contact the researcher (the author) through either phone or email. Follow up calls were made to ensure that the system had been installed properly and was operational. During the study period, the participants measured their blood glucose at least four times a day, or more as directed by their diabetes health care provider using the glucose monitor provided to them for the study. The measurement procedure involves the use of a lancet for penetration into the skin to obtain a blood sample. The sample is then transferred to a test-strip to be used in the meter.

They were not required or suggested to make any changes to the steps they take for measuring their blood glucose level or to their normal routine for managing their diabetes for this study or to base it on the color of the Health-Zero Orb.

The participants could look at the Health-Zero orb to remind themselves of their most recently measured blood glucose level. If the participant's friend or family member was also involved in the study, the Health-Zero orb given to him or her by the participant also displayed the same color as the participant's orb and provided information about the participant's most recently measured blood glucose level.

Visit 2

At visit 2 (the end of the study), the participants had to bring back all the devices provided to them for the study including the glucose monitor they used for taking their blood glucose level. The participants completed another survey that included questions about their adherence to self-care using the self-care inventory, social support and basic questions regarding the use of the Health-Zero orb and their satisfaction with it. If the participant's friend or family member had used the Health-Zero orb, the participant had to fill an additional survey about the perceived reaction of their friend or family member to the orb. A short interview with the researcher gave the participants a chance to share any stories related to the use of the orb. The participants had the option of keeping this glucose monitor once the memory was downloaded.

For patient confidentiality, it was ensured that all interactions of the researcher with the study participants were at the Joslin Diabetes Center. All personal information related to the participants was kept confidential and the participants' name did not accompany the data in accordance with HIPAA guidelines.

Participation Benefits

A monetary compensation of ten dollars was given to the participants for every study visit. Thus on study completion, a total compensation of twenty dollars was provided. Free parking was also provided. All study devices provided needed to be returned but an option was given to the participant to keep the glucose meter and the serial cable. The glucose meter and the serial cable together were of a total value of \$100. The participants were also provided with test strips for use during the study. The test strips were of a value of \$83.

5.2.4 Measures

Instruments used for measurement consisted of a baseline measurement questionnaire, a system evaluation questionnaire and questionnaires related to diabetes care behavior and social support. The questionnaires contained both objective measures as well as subjective questions to assess the state of the individual. Communication between the researcher and the participant during the study and a short qualitative interview at Visit 2 also formed part

of the measurement. These were essential for determining the subjective reaction of the participant and discovering system usability problems. All the questionnaires have been provided in Appendix G. The questionnaires used for the study were:

Baseline Report (see Appendix G1): The baseline report was used to gather demographic and socioeconomic data. It also has questions regarding their diabetes and use of digital technology including computers.

Self-Care Inventory (see Appendix G2): Self Care Inventory was used to measure diabetes self-care and adherence to various aspects of the diabetes regimen. It consists of 15 likert-type scale items that measured adherence to various aspects of the diabetes regimen including insulin shots, glucose testing, diet, and exercise.

Social Support (see Appendix G3): The Multidimensional Scale of Perceived Social Support was used to measure the perceived social support from family, friends and significant others (Zimet, 1988). It is a 12 item instrument with an internal consistency with an alpha of .91 and has good validity (Zimet, 1990). Respondents answered each question using a 7-point rating scale ranging from 'very strongly disagree' to 'very strongly agree'. The focus is on the subjective evaluation of support providers rather than on the support function. Perceived social support was used instead of actual social support behavior as only the participants were approved to be given a questionnaire.

Device Usage Questionnaire - Personal (DUQP) (see Appendix G4): The DUQP was a questionnaire designed by the researcher to measure the actual response of the participant towards the Health-Zero orb and its usefulness in the participant's self-care. It used 17 likert-type scale items and had items related to the participant's overall impression of the orb to its effect on individual aspects of diabetes self-care including insulin shots, glucose testing, diet and exercise. The ratings ranged from being positive, neutral or non-supportive to assess the effect of the orb on a wide range of supportive or non-supportive behavior. It also included open-ended questions pertaining to the use of the device, the participant's subjective feeling towards the orb and possible improvements. The questionnaire was not validated or checked for internal consistency due to time restrictions.

Device Usage Questionnaire – Family (DUQF) (see Appendix G5): The DUQF was an instrument designed by the researcher to measure the response of the friend or family member to the Health-Zero orb as perceived by the participant. It measured the perceived usefulness of the orb in inducing change in the support provided by the friend or family member to the participant in managing his or her diabetes. It had 17 likert-type scale items that had items related to the friend or family member's overall impression of

the device to its effect on specific support behavior provided by the friend or family member towards the participant's diabetes self-care. Each response was rated for the degree of effect the orb had on the supportive behavior. It also included open-ended questions pertaining to the use of the device and the friend or family member's subjective feeling towards the orb. The questionnaire was not validated or checked for internal consistency due to time restrictions.

5.2.5 Role of the Researcher

Since one of the aims of the study was to evaluate the usability of the system and facilitate re-design for a statistically significant follow up study, the researcher was not neutral in the study but acted as a facilitator in the use and installation of the system. The researcher guided the participants as needed during installation through emails, phone calls and home visits. Regular contact was kept with the participant to ensure that the system was operational. This allowed the study coordinator to better understand the target population. It also provided him with a mechanism to understand the skill set and knowledge required for the efficient use of the system and evaluate system usability.

5.2.6 Data Analysis

Since this was a pilot study with only 12 participants, the results were not expected to be statistically significant. However for calculating means and other statistical procedures, a standard statistical analysis software SPSS was used. To test the hypothesis, comparisons were made between the level of adherence to self-care and perceived social support at baseline and at follow-up (15 days). The level of adherence to self-care was measured using the aggregate score of the self-care inventory while perceived social support was measured using the aggregate score of the multi-dimensional scale of perceived social support. Missing values were replaced by the mean of the series using a standard statistical analysis software SPSS. Analysis was also done on individual constructs obtained from the self-care inventory and the social support questionnaire to observe the effect of the intervention of the Health-Zero orb on diabetes self-care.

Apart from the overall testing of the hypothesis, the analysis was also conducted on a case basis. This was important to emphasize the individuality of the experience with the Health-zero orb and the fact that the Health-Zero orb was a mechanism by which the environment becomes a medium of exchange of health information. The same environment can hold different meanings to different individuals.

5.3 Study Recruitment

5.3.1 Study Sample

The study sample comprised six males and six females (twelve participants). The participants were diverse in age, marital status and duration of diabetes but homogenous in ethnicity, degree of social support and self-care. The participants were primarily White or Caucasian with one Puerto Rican as compared to the general diabetes population.

All the study participants were well educated and had a high socioeconomic status. They were students, employed or retired. All the participants reported receiving a high degree of support from friends, family members or significant others. Eight participants had type 1 diabetes, one had type 2 and used insulin while three had type 2 diabetes but did not use insulin. The duration of diabetes (since diagnosis) ranged from 2 months to 21 years. None of the participants except one had any complications of diabetes. The scores obtained from the self-care inventory indicated a high self-care behavior. Six participants chose to give the orb to a friend and family member. The participants who chose to give the orb to a friend or family member did not differ in socio demographic characteristics, self-care behavior or perceived social support from the other six participants.

5.3.2 Flow of Participants

Figure 5-2 shows the flow of participants through the study. Approximately 900 people from the Joslin Clinic Population who had medical appointments between 7 July, 2004 to 15 July 2004 were mailed brochures and personal letters (Appendix D) inviting them to participate in the study. The brochures and letters provide basic information regarding the study, eligibility criteria and contact information. From the total of 900 letters mailed, only 2% of the potential participants responded of which two respondents were found to be not eligible for the study and two respondents decided not to participate in the study. Three people responded to brochures at the Joslin Diabetes Center out of which two decided to participate in the study. An unknown number of respondents were lost due to a problem in the voice mail system of the Joslin Diabetes Center. From the twelve participants who participated in the study, two were recruited through wall postings, four through personal letters, five at the recruitment table and one through a personal referral.

Out of the twelve participants who joined the study, eight participants were able to complete the intervention. Three of the eight participants who completed the intervention decided to provide another orb to a friend or family member.

Non-respondents

Some of the patients at the Joslin Diabetes Center mentioned the need for having a computer and a high-speed internet connection as a major barrier for them not being able to join the study. This was corroborated by one of the study participant who commented that it is better for the Health-Zero system not to involve the home computer as a lot of the aged individuals do not have a home computer. Another non-respondent mentioned the low compensation as the reason for her not to join the study. Parents also had an active interest in using this device to monitor the blood glucose level of their children. However, the eligibility age requirement prevented their participation in the study.

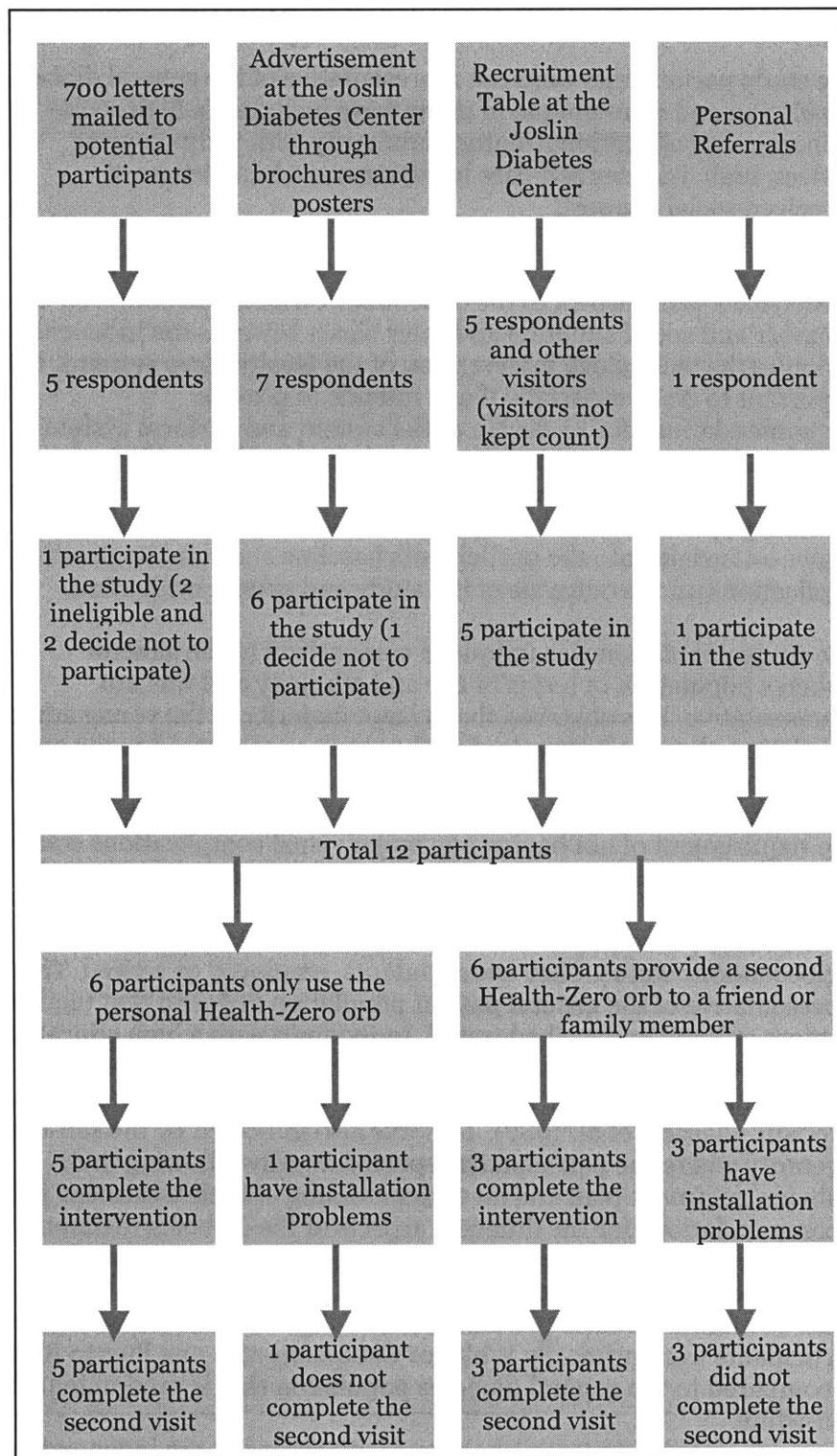


Figure 5-3 Flow of Participants for Diabetes Orb Study

5.3.3 Understanding Sample Population

The study participants were not representative of the general diabetes population and were unique in many ways including a high socio-economic and educational status, familiarity with technological devices, high diabetes self-care behavior and a high degree of perceived social support.

It is important to understand the baseline characteristics of the participants with respect to the dependent variable (diabetes self-care behavior and social support) and their biases towards the independent variable (the technology intervention of the Health-Zero system). It is important to do so especially if one intends to provide recommendations for re-design of the system and perform system usability. The recommendations and results would be valid for a population that is represented by the participants and not the general diabetes population. Thus in this section we analyze the participants to give an insight into the participants baseline state and its possible implications on the outcome of the study and system evaluation.

The study population was unique in comparison to the general diabetes population in terms of age and ethnicity and was not representative. It is observed that a large majority of the young adult population chose to be involved in the study as compared to the aged population. The eligibility criteria of being able to use a computer and have a high-speed internet connection could be the possible reasons. The requirement of not having any major visual complications could be another reason that would reduce aged participants.

All the study participants were well educated and had a high socioeconomic status. They were students, employed or retired. This is representative of the general patient population at Joslin that tends to be more affluent and well educated. Individuals with a high education and socio-economic status are also more probable to have received formal diabetes education and have better adherence to diabetes care (McCaul, Glasgow et al. 1987). This was also indicated by the self-care inventory where the participants reported usually following their diabetes treatment plan and an understanding of their treatment plan recommendations for the different aspects of the diabetes regimen: glucose monitoring, exercise, medication, meal plan, medical appointments and treating lows. It is to be mentioned that a high socio-economic status is correlated with a high education status. The participants were primarily White or Caucasian with one Puerto Rican as compared to the general diabetes population that is predominantly non-white.

The study population was also unique with regard to the independent variable, the technology intervention of the Health-Zero system. Here we describe the specific unique characteristics of the target population in terms of the domains of observation of the individual that are of interest to us in the study: affective, cognitive and interpersonal domains. The affective domain is important to determine the attitude

of the participants towards technology while cognitive domain has implications in understanding the results of system usability. The baseline characteristic of the participants along the interpersonal domain gives an idea of the way the study participants used technology to interact with individuals in their social network.

Affective Domain: The participants had a positive attitude towards using new technology and had characteristics similar to those of early adopters of technology. Many studies have found that early adopters of innovations are more likely to be highly educated and of higher socioeconomic status (Dickerson and Gentry 1983) as compared to non-adopters. Higher income status also correlates with more experiences with technology, specifically computers (Dickerson and Gentry 1983). The findings were corroborated by the demographics of the participants. Previous experience with technology is considered to increase the likelihood of using new technology (Dickerson and Gentry 1983). The study sample indicates that the participants had usage and experience with home computers and other digital products. One cannot make judgments about the non-respondents at this stage. Some of the above characteristics like the use of computers were predetermined by the eligibility criteria itself. But it is significant that the other demographic characteristics matched the demographics of early adapters.

Cognitive Domain: A higher level of education correlates with a better understanding of systems, making the systems more desirable and easier to use. This increases system usability. The study participants had the necessary skill set required for installing software and using a technological system. As corroborated by the results in section on system usability, such a population would also probably be persistent in the use of the system and will try to correct problems rather than give up. They have an “I can do it” attitude towards technology.

Interpersonal Domain: All the participants (by the eligibility criteria) had access to the internet. They all had email accounts and used cell phones. Although one cannot make major judgments as we did not gather data regarding the frequency of use of email or cell phones, but it can be said that the study participants were open to the use of technology as a facilitator for interaction and information exchange.

5.4 System Anomalies

At the beginning of the study it was discovered that the Java Runtime Environment has a bug in it where a graphical window is displayed using Microsoft's draw functions, it increases the CPU usage to 100%. Due to it the program was rewritten to be completely textual without graphical displays. Thus, even the basic windows that provided information about the system had to be removed! At the time of discovery of the anomaly, three participants had enrolled in the study but had not installed the system. They were provided with new installation CDs.

5.5 Study Results

The analysis of a technology needs to be based on the different transformations that happened within individuals due to their interaction with the technology. The results are presented for the interaction of the participants with the Health-Zero orb in the different domains of observation: cognitive, interpersonal, affective and moral. The effect of the interaction between the participants and the Health-Zero orb along the cognitive domain formed the basis of hypothesis 1a while hypothesis 1b was based on the interaction along the interpersonal domain. These results form the basis of analysis of the effect of the intervention on diabetes self-care in Section 5.2.5.

The results are based on eight participants who had an operational Health-Zero orb irrespective of the intervention required by the researcher during the installation. Three out of the eight participants provided a second Health-Zero orb to a friend or family member. Table 5-1 provides an overview of this data. Two of the participants (participant 9 and participant 11) had the second Health-Zero orb with a family member in the same home as the Personal Health-Zero orb while one participant (participant 10) gave the second Health-Zero orb to a friend who lived in a different location.

Participant Number	Installed Without Difficulty	Operational	Second Health-Zero Device
Participant 1	✓	✓	
Participant 2			✓
Participant 3	✓	✓	
Participant 4			
Participant 5		✓	
Participant 6		✓	
Participant 7			✓
Participant 8			✓
Participant 9	✓	✓	✓
Participant 10		✓	✓
Participant 11	✓	✓	✓
Participant 12	✓	✓	

Table 5-1 Health-Zero System Status of the Participants

5.5.1 Results: Cognitive Domain of Observation

In this section, the results are presented to demonstrate the interaction between the individual and the participant in the cognitive domain. The Health-Zero orb was designed to improve participants' cognitive domain in diabetes care by providing them with a visualization tool. It was hoped that this would lead to better diabetes

self-care behavior by providing easy access to information about their current blood glucose levels. This formed the basis of hypothesis 1a.

Data Visualization: Results for Hypothesis 1a

Hypothesis 1a received support with six of the eight participants who used the Health-Zero orb reporting increased adherence to diabetes self-care behavior at follow up as compared to their baseline self-care behavior. The relevant data is presented in figure 5-4. The self-care behavior is reported as the aggregate score of the self-care inventory (Appendix G). The scores have been normalized by the maximum possible score that was possible for each of the participants. This maximum differed based on the type of diabetes of the participants: type 1 or type 2 and on the number of questions they answered on the self-care inventory. It is important to note that here an individual with a 100 percent on the self-care inventory corresponds to them “always” following every aspect of their diabetes treatment plan. This may be obsessive if disease management became the focus of the life of a person with diabetes. In contrast, a score of 70-80% corresponds to a person with diabetes “usually” doing all the things that he or she should do to manage their diabetes well. Most of the subjects were in this group both at baseline and at follow up.

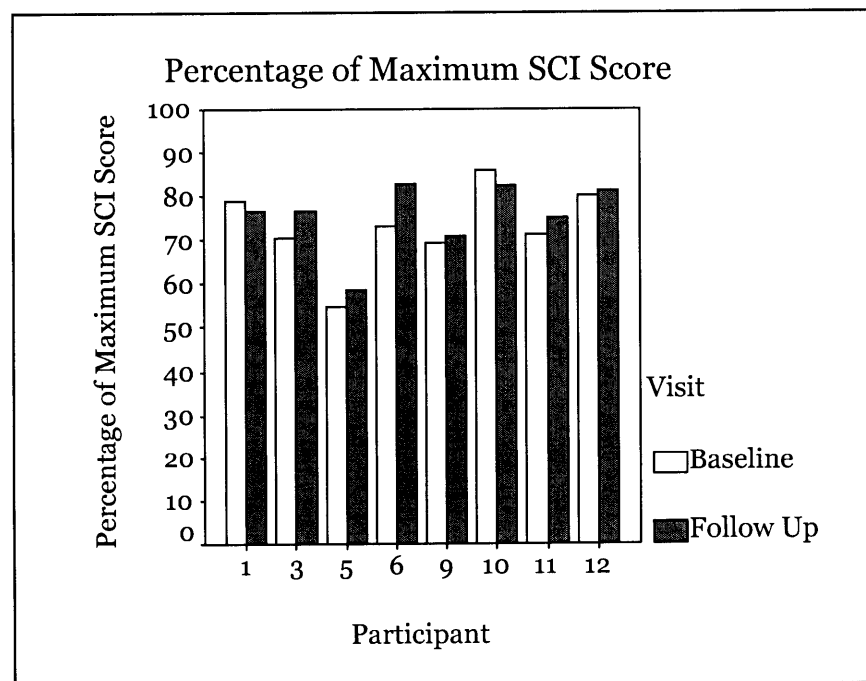


Figure 5-4 Percentage of Maximum SCI Score of the Participants at Baseline and Follow Up

Although the results of improvement from baseline are positive and show a positive trend towards statistical significance, the sample population is too small for the results to be statistically valid. The experiment was also not controlled for the effect of participation in the

study. In cases of participant 3 and participant 6, the improvement in the self-care behavior was statistically significant. Participant 3 had joined a Diabetes Camp during the study period and Participant 6 shifted from a manual insulin injection to an insulin pump. Both these factors would lead to increased self-care.

The participants were also asked to rate the helpfulness of the Health-Zero orb in their diabetes self-management and its influence on specific aspects of the diabetes regimen: meal plan, medication, exercise and glucose testing. A majority of the participants (seven of the eight participants) rated the Health-Zero orb as being 'useful' or 'very useful' in helping them manage their diabetes. Six of the eight participants rated that the Health-Zero orb 'helped' remind them of their blood glucose levels. There was an equal distribution of responses on the influence of the orb on other aspects of the diabetes regimen: meal plan, medication and exercise. None of the participants rated the Health-Zero orb to have a negative influence on their diabetes self-management. Six of the eight participants rated that it was easy for them to interpret their blood sugar levels as a color than as a number. Table 5-2 summarizes the responses of the participants.

2. Did the orb remind you of your blood glucose level?	Never	Rarely	Sometimes	Usually	Always
			■	■ ■ ■	■ ■ ■ ■
3. Did you find the orb helpful in taking care of your diabetes in general?	Very Useful	Useful	Not Useful	Got In The Way	
	■	■ ■ ■ ■ ■ ■ ■			
4. Did the orb influence your diabetes self-care by:					
Reminding you to make better food choices?	Helped A Lot	Helped	Did Not Help	Got In The Way	
	■	■ ■	■ ■ ■ ■ ■		
Reminding you to take your medicine and insulin?	Helped A Lot	Helped	Did Not Help	Got In The Way	
	■	■ ■ ■	■ ■ ■ ■ ■		
Reminding you to increase your activity?	Helped A Lot	Helped	Did Not Help	Got In The Way	
		■	■ ■ ■ ■ ■ ■ ■		
Reminding you to check your blood glucose?	Helped A Lot	Helped	Did Not Help	Got In The Way	
	■ ■ ■	■ ■ ■	■ ■		
6. Was the orb useful?	Very Useful	Useful	Not Useful	Got In The Way	
	■	■ ■ ■ ■ ■ ■ ■			

8. How difficult was it for you to interpret the colors on the orb for your blood sugar level?	Very Hard	Hard	Normal	Easy	Very Easy
			■ ■	■ ■ ■ ■	■ ■

Table 5-2 Cognitive Evaluation of the Health-Zero Orb: Personal Deice Usage Questionnaire

This is also corroborated by the written comments from participants that indicated that the color on the Health-Zero orb influenced their diabetes self-care behavior by reminding them of their blood glucose level and the need to maintain their blood glucose level. Some of these comments are presented below in Table 5-3. The color played a very strong role in the way the participants used the Health-Zero orb as is visible in some of the comments below.

If the orb was red. It reminded me of my blood glucose level. It reminded me that I am forgetting something that I should be doing.

The color reminded me of my most recent reading.

It was fun to look at night, it would flash red, and I couldn't sleep, so I would take more insulin until it was the right level.

It reminded me of how poorly I manage by diabetes.

It reminded me to check my blood sugars and helped keep my diabetes care on my mind.

Provided reminder of glucose levels.

Quick check on blood sugar status.

I found it was a reminder of my glucose levels but also was a reminder to check my blood sugars, take my pills and sometimes even to eat regularly when I felt I was "too" busy.

Made me more aware of the level of my blood glucose. Easier to see a color than look at a number and then determine the range (high-ok-low).

When it was Red, I thought about it properly. Red is the pay attention color.

Numbers come and go. I could not tell you what my blood sugar was but I might remember if it was blue. Actually, I remember last morning it was yellow.

Color is Boolean. It is very easy to comprehend and you need not know the nuances of diabetes.

Table 5-3 Cognitive Evaluation of the Health-Zero Orb: Subjective Comments of the Participants

Task Complexity Results

The participants did not report any difficulty in understanding the use of the device or the installation procedure. All the participants reported that the Health-Zero orb was easy to install. As mentioned earlier, the study participants were not representative of the general population but represented individuals who were early adopters, had a positive attitude towards use of technology and perceived systems to be less complex. They possessed the necessary skill set to install and use a moderately technical system efficiently. One participant had initial difficulty in the use of the glucose meter as she was not familiar with the LifeScan Ultra glucose meter. However once properly demonstrated, she did not face any difficulty in its use. The competency of the participants is also corroborated by the fact that those participants who had installation problems were able to understand and follow the instructions provided to them by the researcher by telephone. It may be the case that this is a particularly competent population and that the same system could be perceived as difficult to use by the general diabetes population.

System Usability Results

The field-testing of the system highlighted several issues regarding usability of the system during installation and later ongoing usage.

The major issues faced during the installation were a lack of response from the system for successful completion of sub-tasks and dependency on the participants' home computer. The participants did not know if the system was operational until they had completed the installation procedure and the Health-Zero orb changed to the specific color according to their blood glucose level. The whole installation procedure took 15 - 30 minutes. At times, the researcher had to contact the participants to inform them that the system was operational or not operational. This was especially problematic if the participant was trying to debug the system without the researcher's intervention. One participant did not connect Device 2 (Bluetooth transmitter) properly to the computer but successfully installed the client software. Various attempts to debug the problem over emails and phone failed. It was only after a personal visit to the participant's home that the problem was understood. A specific response from the system about the failure to complete a particular task would have made it easier for the participant to install the system without the intervention of the researcher. Throughout this section, I present representative comments by participants.

"Incorporate some kind of confirmation that allows the user to know when reading has been sent to the server/orb."

**Table 5-4 System Usability Comments for the Health-Zero System:
Lack of Feedback**

The second problem that arose was the dependency of the Health-Zero system on the participants' home computer. It greatly increased their workload in installing the Health-Zero system and restricted the participant population to computer owners. At the same time, it increased the chances of error during installation and use. During the development of the Health-Zero system, the system was tested on an environment with Windows 2000 with no internet firewall or proxy required to access the internet. However, participants' system configurations differed. Many participants had windows XP or Windows 98 installed on their computer and had internet firewalls. In some cases the desktops required an additional serial cable to connect Device 1 to their computer as the space was limited at the back of the computer.

"Take the computer out of the loop in the system. The computer got in the way."

"It would be great if a self-contained system were developed that didn't require the use of a PC. A lot of older people do not have a PC."

Table 5-5 System Usability Comments for the Health-Zero System: Complicated Interfaces

During installation, the other issues ranged from the failure of three of the Health-Zero orbs to stabilize to a specific color as they were outside the range of the Health-Zero orb network or there was an error in the orb itself. In another system, Device 2 (Bluetooth transmitter) received damage during transportation of the system (loose cabling) and was not initially operational.

During the use of the device, the participants reported two major problems. The first problem related to the delay in the change of color on the Health-Zero orb after the participants had checked their blood glucose levels. The delay in the change of color happened due to the Health-Zero orb network that provided a signal to the Health-Zero orb.

"Orb went out of sync occasionally."

"The lag time between my test (blood glucose level) and the orb changing color was too long."

"Perhaps work on closing the large gap of time between the time that one checks his or her blood sugar and the time that the orb changes color – This would definitely be of more impact."

Table 5-6 System Usability Comments for the Health-Zero System: Time Delay in Change of Color

The second problem related to the mobility and portability of the device. The participants were instructed to place Device 2 (transmitter attached to the glucose meter) in the same room as the computer. Uniform instructions were needed for use of the Health-Zero system. Device 2 could be at a maximum distance of 30ft and individual

conditions could have varied. This seriously limited the mobility of the system to a few feet and imposed an additional constraint on the participants that the glucose meter be in the same room as well. The participants also complained that it was a major burden for them to have to attach the glucose meter to Device 2 (transmitter attached to the glucose meter) which prevented them from carrying the glucose meter or the complete system around.

“Process of plugging transmitter into the meter was bothersome – direct transmission from meter would be desirable.”

“The orb would be much more useful if it was portable (and smaller) unless you are a very immobile person, or work from home – then it would be great.”

“If you could make an orb that doesn’t have to be connected to the glucometer, that would work too.”

“Also, it would be useful to improve the portability of the device. I could only have the orb setup either at work or at home and I feel that it would have been of greater impact if it were something I could use all day.”

**Table 5-7 System Usability Comments for the Health-Zero System:
Lack of Mobility**

5.5.2 Results: Interpersonal Domain of Observation

Social Support: Results for Hypothesis 1b

Hypothesis 1b focused on improvement in the inter-personal domain of the participants by creating a communication channel between them and their friend or family member. It was hypothesized that the second Health-Zero orb provided by the participants to the friend or family member would increase the social support given by the friend or family member to the participants in managing their diabetes. This increase in support along with the use of the personal Health-Zero orb would increase the diabetes self-care behavior of the participants as measured through their response to the self-care inventory.

It is difficult to make statistically sound judgments about hypothesis 1b as only three of the six participants who decided to give a second Health-Zero orb to the friend had their system operational. This presents a very limited data set. Thus even though a minor change was observed in the diabetes self-care behavior of the three participants, it is not clear whether the second Health-Zero orb played any additional role apart from the personal Health-Zero orb used by the participants. Figure 5-5 present the self-care behavior of the participants at baseline and at follow up as measured through the aggregate self-care inventory score. The responses are from the three participants who chose to give another Health-Zero orb to a friend or family member and had the system operational during the study.

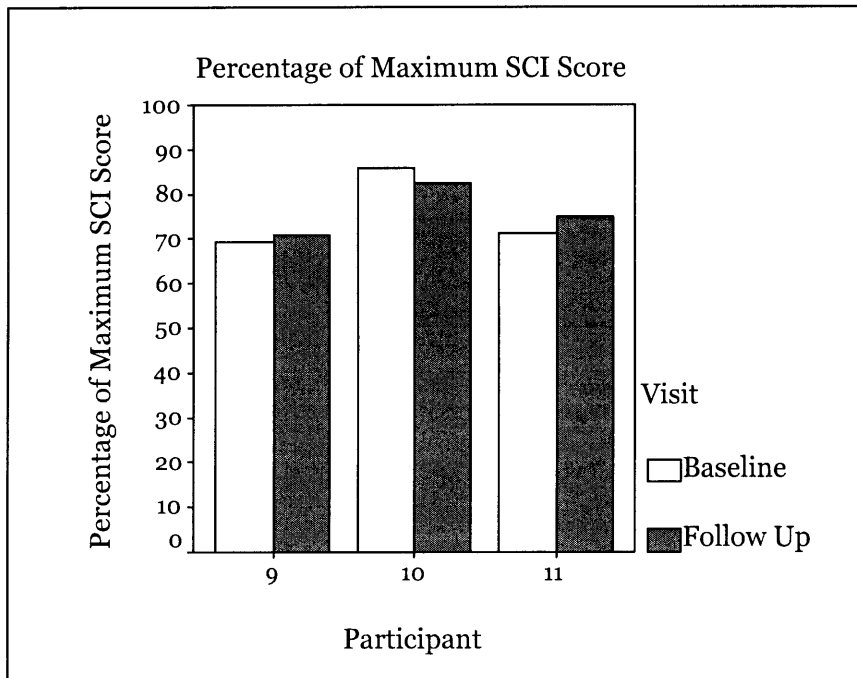


Figure 5-5 Aggregate Self-Care Inventory (SCI) Score of Participants Who Gave a Second Health-Zero Orb to a Friend or Family Member.

It can be seen that there was an increase in the aggregate self-care inventory scores of participant 9 and participant 11 while the score of participant 10 declined. In addition to the questions described in hypothesis 1a, the participants were also asked to rate the helpfulness of the second Health-Zero orb and its influence on the support given by the friend or family member towards diabetes self-care of the participants. Opinion was divided on the influence of the friend or family orb on the support provided by them to the participants. However, all the participants rated that the Family Health-Zero orb helped the friend or family member better know and understand their blood glucose levels. None of the participants reported that the Family Health-Zero orb had a negative influence on the support provided by the friend or family member. The results are summarized in table 5-8.

2. Do you feel the orb helped your friend or family member know your blood glucose level better?	Helped A Lot ■ ■	Helped ■	Did Not Help	Got In The Way	
3. Did the orb in general increase the amount of help your friend or family member gave you in taking care of your diabetes?	Helped A Lot ■	Helped ■	Did Not Help ■	Got In The Way	
4. Did the orb influence the way your friend or family helped you in your diabetes self-care in:					
Reminding you to make better food choices?	Helped A Lot ■	Helped ■	Did Not Help ■	Got In The Way	
Reminding you to take your medicine and insulin?	Helped A Lot ■ ■	Helped	Did Not Help ■	Got In The Way	
Reminding you to increase your activity?	Helped A Lot	Helped ■	Did Not Help ■ ■	Got In The Way	
Reminding you to check your blood glucose?	Helped A Lot	Helped ■	Did Not Help ■	Got In The Way	

Table 5-8 Evaluation of the Friend or Family Health-Zero Orb: Part I

6. Did you find your friend or family's orb useful?	Very Useful ■	Useful ■ ■	Not Useful	Got In The Way	
8. Did your friend or family member's orb influence your diabetes self-care by:					
Reminding you to make better food choices?	Helped A Lot ■	Helped	Did Not Help ■ ■	Got In The Way	
Reminding you to take your medicine and insulin?	Helped A Lot ■	Helped	Did Not Help ■ ■	Got In The Way	
Reminding you to increase your activity?	Helped A Lot	Helped	Did Not Help ■ ■ ■	Got In The Way	
Reminding you to check your blood glucose?	Helped A Lot ■	Helped	Did Not Help ■ ■	Got In The Way	

Table 5-9 Evaluation of the Friend or Family Health-Zero Orb: Part II

Written responses from the participants also indicated that the Health-Zero orb helped the friend or family member in knowing their blood glucose levels. Table 5-10 summarizes the comments.

“It was easier for her (friend or family member) to understand the information.”

“They (friend or family member) thought it was fun to use. They felt empowered because they were able to recognize when my (the participant) blood was low.”

“It helped my five year old daughter know what my blood glucose level was. It especially helped her recognize when by blood glucose was low. It was very easy to understand that Daddy’s blood is low.”

“I gave the second orb to a friend who lives about 15 miles away. He called several times when it turned blue.”

“I thought it was helpful. They could notice the changes in the color and comment on them. It was an encouragement to stick with my diet pills and routines.”

Table 5-10 Interpersonal Evaluation of the Friend or Family Member Health-Zero Orb: Subjective Comments of Participants

Social Support and Personal Health-Zero Ambient Orb

The personal Health-Zero display that the participants used themselves was also a source of conversation between the participants and the visitors with seven of the eight participants rating that visitors to their home would ‘usually’ or ‘always’ ask about the Health-Zero orb (table 5-11).

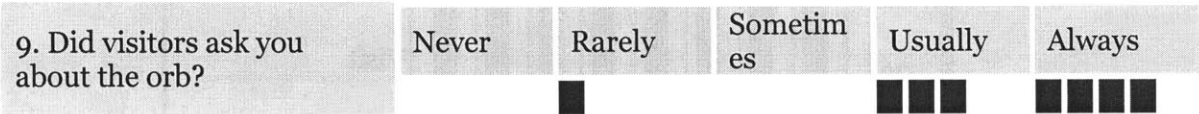


Table 5-11 Interpersonal Evaluation of the Personal Health-Zero Orb

Some of the comments reported by the participants confirm this. For participant 3, the personal orb became a feedback channel with the visitors commending him on his blood glucose control (when the personal Health-zero orb was green). Table 5-12 summarizes the responses.

“They (visitors) would come and pat me on the back if the color on the orb was green the whole day.”

“They (visitors) thought the colors were neat.”

“It (personal orb) was pretty. They (visitors) liked it. Nice Colors. Good to see how I (participant) was doing my control.”

“Very inquisitive (the visitors were very inquisitive).”

“Everyone thought it was very neat. My parents were hopeful it would help and my friends just wanted to see it change colors.”

Table 5-12 Interpersonal Evaluation of the Personal Health-Zero Orb: Subjective Comments of Participants

All the participants were also measured on the degree of social support perceived from friends, family members and a special person using the social support questionnaire (Appendix G). Figures 5-6, 5-7, 5-8 and 5-9 present the results. Participant 7, who did not complete the intervention, did not report any substantial change in the overall social support. It is to be noted that participants 9 and participant 11 gave a second Health-Zero orb to family members who were living with them while participant 10 had given a second Health-Zero orb to a friend.

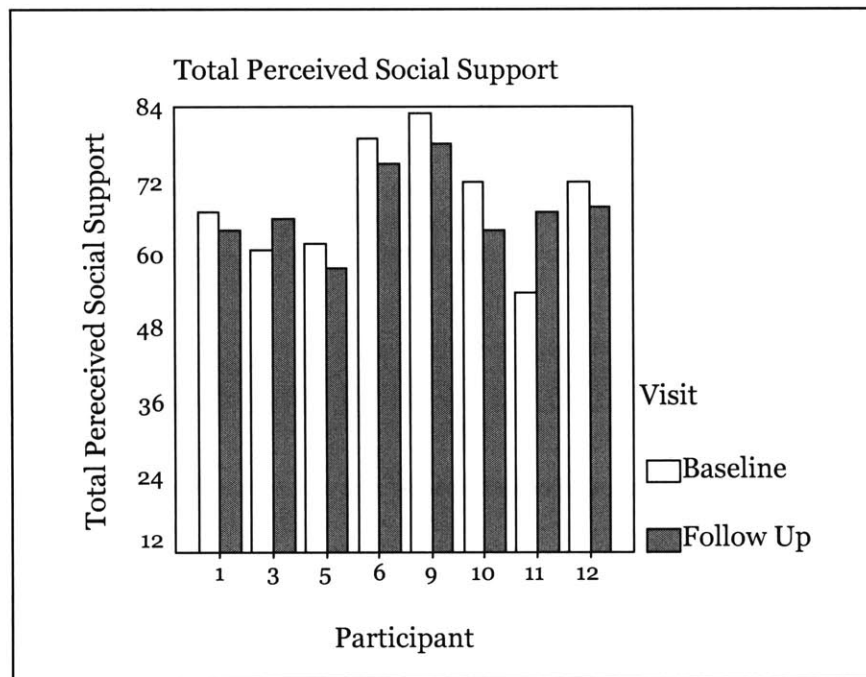


Figure 5-6 Total Perceived Social Support by Participants at Baseline and Follow Up

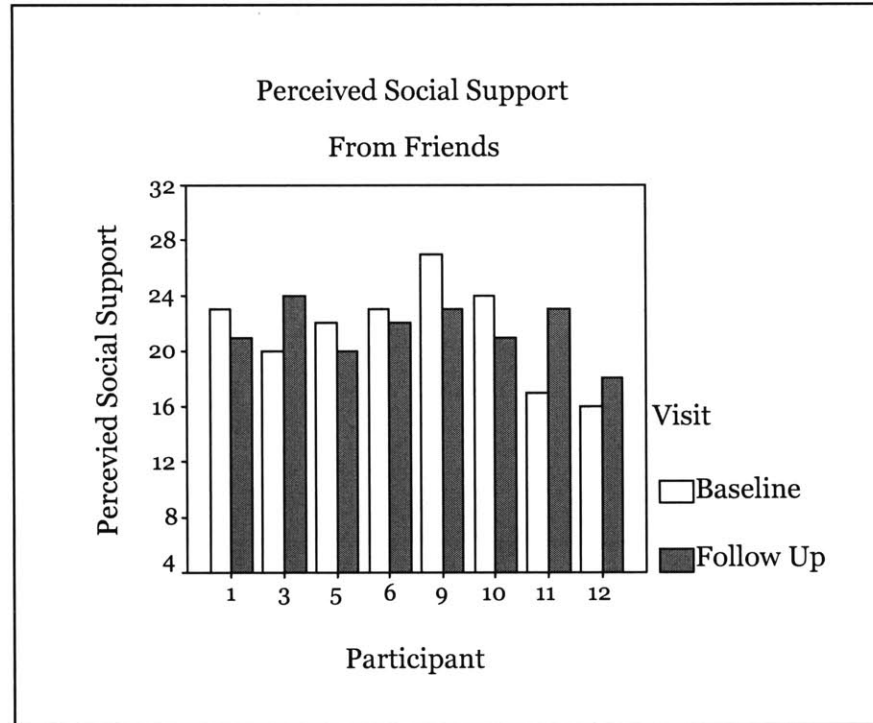


Figure 5-7 Perceived Social Support from Friends by Participants at Baseline and Follow Up

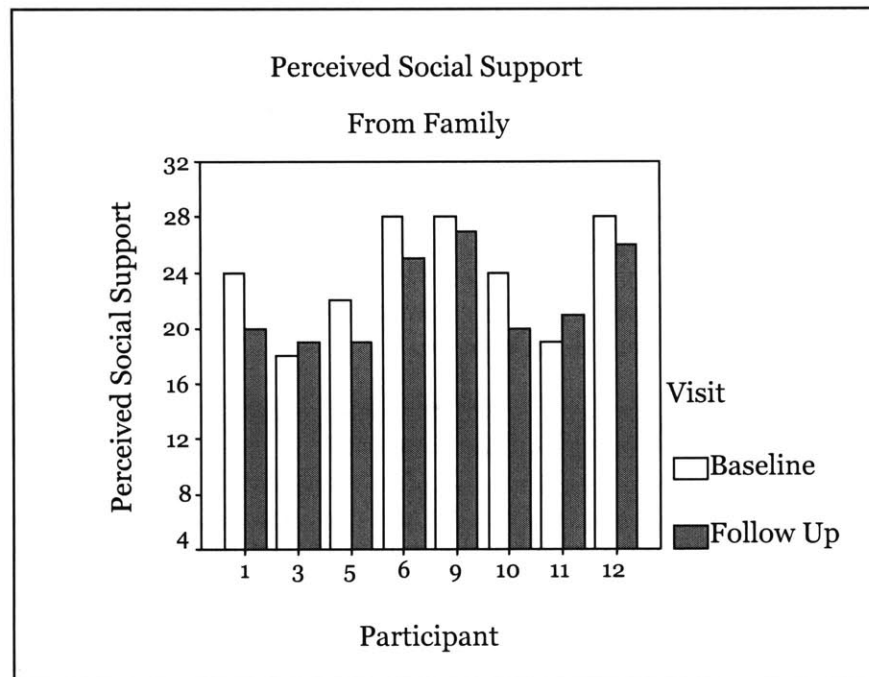


Figure 5-8 Total Perceived Social Support from Family Participants at Baseline and Follow Up

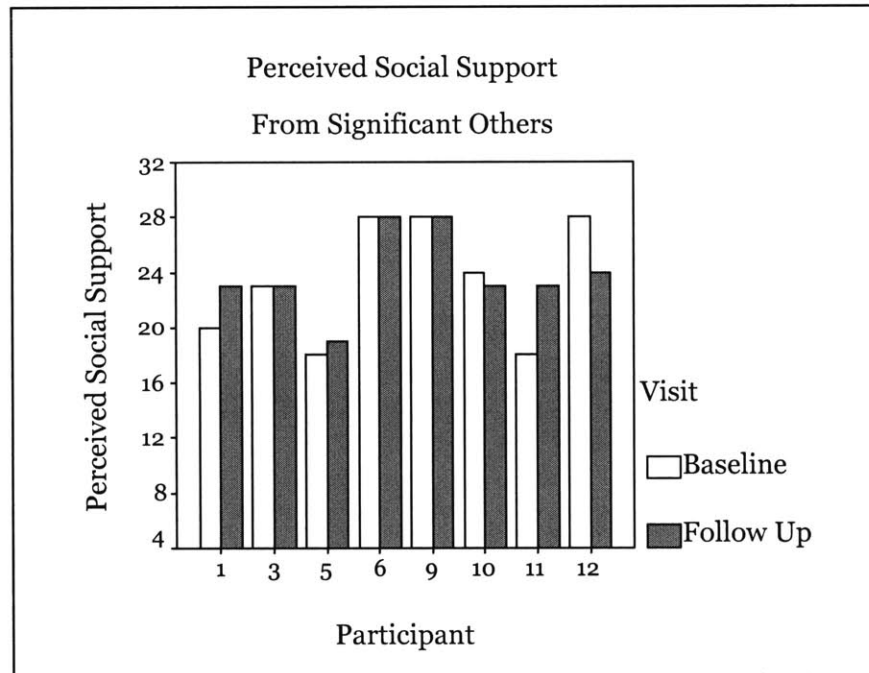


Figure 5-9 Total Perceived Social Support from Significant Others at Baseline and Follow Up

Six of the eight participants reported a decline in the overall perceived social support as measured by the social support questionnaire (Appendix G3) (the exceptions were participants 3 and 11). The overall social support can be further divided into constructs of social support based on the origin of social support: friends, family or a special person. The participants (except Participant 3 and Participant 11) reported a decline in the social support received from friends and family members. The change in the perceived social support from a special person was mixed: it variously declined, stayed constant or increased. During personal interviews, participants 3 and 11 related their experiences of the way the Health-Zero orb helped increase social support from the friends or family members towards their diabetes care.

“They (visitors) would come and pat me (participant 3) on the back if the color on the orb was green the whole day.”

“I (participant 11) thought it was helpful. They (family members) could notice the changes in the color and comment on them. It was an encouragement to stick with my diet pills and routines. I didn’t think it was that low. It was on the lower end but didn’t think it was that low. It’s not supposed to be blue, mom.”

Table 5-13 Interpersonal Evaluation of the Personal Health-Zero Orb: Subjective Comments of Participants

This reinforces the fact that the Health-Zero orb impacted the social support received from friends or family members. It is however unclear whether the impact was positive or negative. There seems to be a contradiction with the participants reporting a general decline in the overall perceived social support while at the same relating experiences of the usefulness of the Health-Zero orb in helping friend and family members understand the blood glucose level.

5.5.3 Results: Affective Domain of Observation

The participants liked using the device and felt that it was fun to use. Table 5-14 summarizes the response of the participants.

1. How did you feel about the orb?	Loved It	Liked It	No Opinion	Annoyed Me	Hated It
	■ ■	■ ■ ■ ■ ■ ■ ■			
5. Was the orb fun to use?	Never	Rarely	Sometimes	Usually	Always
			■		■ ■ ■ ■ ■ ■ ■ ■

Table 5-14 Affective Evaluation of the Personal Health-Zero Orb

The participants were very positive about the use of color as a medium to express their blood glucose level. The participants strong stated (in comments) that the number associated with the blood glucose reading has a strong feeling associated with it. In diabetes it is important that the blood glucose level be within a certain target range rather than a specific number (for more information, see Appendix K).

- “When I take my blood sugar in the morning. I was always concerned about if was 97 or 103. I wanted it to be below 100. But the color says you are OK. They are both green. Don’t worry about it. I didn’t worry about the number.”
- “Numbers come and go. I could not tell you what my blood sugar was but I might remember if it was blue. Actually, I remember last morning it was yellow.”
- “Color is Boolean. It is very easy to comprehend and you need not know the nuances of diabetes.”
- “The number (blood glucose reading) is like a test score. You have to do well on it. Diabetes is a chronic disease. You see that number day in and day out. It burns you out. Anything that helps shift the focus is good. The color helped me shift the focus.”

Table 5-15 Affective Evaluation of the Personal Health-Zero Orb: Subjective Comments of Participants on Number vs Color to Represent Blood Glucose Levels

The Health-Zero system was designed in a way that the color on the Health-Zero orb was green if the participants' blood glucose level was within the normal target range (for details please see Appendix I). The Health-Zero orb was blue if the blood glucose level was too low and red if it was too high. The participants reported that the choice of the color was very important and the red color on the Health-Zero orb was instrumental in making them attentive to their diabetes self-care. They reported that red is considered a sign of danger in United State and that prompted them to react more to the Health-Zero orb when it was red. According to the participants if the colors were reversed in their roles with green being bad and red being good, this would have significantly affected their response to the Health-Zero orb and the ease of use of the system.

"My favorite is Blue. So I intentionally dropped it (my blood glucose level) low when I used it the first time to see the blue color. I would have liked if instead of green it was blue. I would want to keep it blue all times."

"When it was Red, I thought about it. It's the pay attention color."

"It is like a game. It gives you incentive if you liked the color."

**Table 5-16 Affective Evaluation of the Personal Health-Zero Orb:
Subjective Comments of Participants on Use of Color to Represent
Blood Glucose Levels**

5.5.4 Results: Moral Domain of Observation

During the personal interview with the researcher, the participants were also asked about their views about the transmission of the blood glucose range over the internet. As previously mentioned, the information about the color corresponds to the blood glucose level that was transmitted over the internet to the Health-Zero orb network. The network then transmitted the color value to the Health-Zero orb. None of the participants reported any major privacy-type fears related to the transmission of the blood glucose ranges over the internet. The responses ranged from being indifferent about it to being satisfied with the fact that only the color value (the range) was transmitted and not specific glucose values. It is to be noted that the researcher did not suggest to the participant possible negative or positive uses of this information. A possible positive use would be to send this information to the healthcare provider who can keep a record of this information. A possible negative use would be to give this information to insurance companies who use it to change the medical coverage (if it is permissible by law).

Another issue that arose during the study was if the Health-Zero orb could be used at the office. Here it becomes important whether participants would feel comfortable letting their co-workers know that they have diabetes. Due to the study protocol, I recommended to the participants

that they use the Health-Zero orb at home. But this raised an important question of how participants viewed using the Health-Zero orb at work. This question was asked during the personal interviews with participants. The response regarding sharing of blood glucose levels with co-workers ranged from being positive to being apprehensive. One of the participants who had frequent hypoglycemic episodes reported that it is important for the co-worker to know about his or her condition of hypoglycemia, as they would feel empowered by the knowledge that the participant is having such an episode and they can help. It is to be noted that during severe hypoglycemia, an individual can act abnormally or even become unconscious. Another participant commented that she would not prefer to keep the orb in the office as she was not sure if she would prefer to have her co-workers to know that she has diabetes.

"If it was a specific number, I might have a problem. But color is not specific. I do not have a problem with that being transmitted."

"I am not really afraid of the internet. I would not really care."

"Ok for me. I don't care. They are just numbers."

"Usually I am not paranoid. What are they gonna do with it?"

"The more people who know my readings, the better. This puts people around me in a position to help me if my blood sugar is low."

I don't know if I would want to keep it at office

Table 5-17 Moral Evaluation of the Health-Zero System: Subjective Comments of Participants

5.5.5 Results: Overall Experience

In summary, the participants had a positive experience with the Health-Zero orb. The response was measured on the willingness of the participants to use the Health-Zero orb in the future, their frequency of use and their overall experience with the Health-Zero ambient display system. Participants reported that they enjoyed using the device. Figure 5-18 summarizes the overall experience of the participants. The responses of the participants who had installation problems did not differ substantially from the responses of the participants who did not report any installation problems. Another measure of the overall experience with the Health-Zero orb was the desire of the participants in using the system in the future. All the eight participants who used the Health-Zero ambient display system reported that if the system usability issues were removed they would use the device again in the future. It is important to note that the 'yes' was conditional on the removal of the system usability issues.

	Never	Rarely	Sometim es	Usually	Always
5. Was the orb fun to use?			■		■ ■ ■ ■ ■ ■ ■
7. How often did you look at the orb?			■	■ ■ ■	■ ■ ■ ■

Table 5-18 Overall Experience of the Personal Health-Zero Orb

Those participants who had given a second Health-Zero orb to a friend or family member also reported that the friend or family members had fun using the second Health-Zero orb and they often used it. Figure 5-19 summarizes the results.

	Loved It	Liked It	No Opinion	Annoyed Me	Hated It
1. How did your friend or family feel about their orb?	■	■ ■			
	Never	Rarely	Sometim es	Usually	Always
5. Do you feel the orb was fun to use by your friend or family?				■	■ ■
	Never	Rarely	Sometim es	Usually	Always
7. How often do you think your friend or family looked at their orb?				■	■ ■

Table 5-19 Overall Experience of the Friend or Family Member Health-Zero Orb

The comments from the participants corroborated the above empirical findings.

“Yes. It (personal orb) was a lot of fun.”

“Fun to look at (personal orb).”

“It (personal orb) is like a game. It gives you an incentive if you liked the color.”

“It (the family orb and the personal orb) became a game between me and my wife. One became her orb and one became mine. She would try to see which orb changed faster.” (both the orbs were located in the same home)

Table 5-20 Overall Experience of the Health-Zero Orbs: Subjective Comments of the Participants

5.5.6 Other Unexpected Results

Seven of the eight participants chose to put the Health-Zero orb in the kitchen or a place at home from where it was visible from the kitchen. Based on the comments of the participants, the participants needed to check their blood glucose level in the morning before eating and thus the kitchen served as a suitable place for it.

Placement of the Personal Health-Zero Orb			
Desk	Desk (Bedroom) (visible from kitchen)	Desk (Bedroom) (visible from kitchen)	Kitchen
Dining Room	Dining Room	Living Room (visible from the kitchen)	Kitchen
Placement of the Family Health-Zero Orb			
Living Room (personal Health-Zero orb located in a different home)	Living Room (another personal Health-Zero orb present in Dining Room)	Guest Bedroom (another personal Health-Zero orb present in Dining Room)	

Table 5-21 Placement of the Health-Zero Orb

One unintended effect that participants reported was that the Health-Zero orb acted like a night-light. Depending on the participants this was either a problem or was beneficial. The comments in the table below (Table 5-22) present this use.

“The problem was that it prevented me from sleeping at night. I had to put pillows around it. It would be great to be able to turn it off.”
“I liked the glow. It gave a good ambience to the room, when it was blue.”
“It was really helpful in the night. I could see the hallway when I needed to go to the bathroom.”
“It was fun to look at night, it would flash red, and I couldn’t sleep, so I would take more insulin until it was the right level.”

Table 5-22 Alternative Use of the Health-Zero Orb: Nightlight

5.6 Evaluation and Critique

The exploration involved me in at least four different roles: researcher, technologist, entrepreneur and thesis writer. As researcher I performed a feasibility study to test a hypothesis. My evaluation relates to the interpretation of the results and designs of future follow up studies. I designed the system. My motivation here is to learn from the use of the Health-Zero system and suggest improvements. In this role I want to determine the value the exploration created for the participants. As thesis writer I want to see a cohesive story that relates to the framework of integrated health and the lessons one can learn from it.

The study related to the use of technology for a desired transformation in the cognitive domain of observation: self-care behavior of individuals and interpersonal domain of observation: social support. It was remarked in Section 2.2 that the different domains of observation: affective, cognitive, interpersonal and moral are inter-related and have an effect on one another. In this case, the important variables that need to be analyzed along these different domains are the dependent variable (diabetes self-care behavior) and the independent variable (the technology intervention of the Health-Zero orb). The analysis is divided into four sections that relate to the interaction of the participants with the Health-Zero orb in the four domains of observation: cognitive (hypothesis 1a), interpersonal (hypothesis 1b), affective and moral. Within each section, I try to see the effect of the baseline characteristics of the participants and the study itself. The emphasis is on the cognitive and interpersonal domain of observation as the Health-Zero orb was designed to improve these domains of observation.

5.6.1 Cognitive Interaction: Analysis of Primary Hypothesis 1a

Hypothesis 1a received support with six of the eight participants who used the Health-Zero orb had increased adherence to diabetes self-care behavior at follow up as compared to their baseline self-care behavior as shown in figure 5-4. One cannot comment on the statistical validity of the outcome, as the number of participants was too small.

Effect of Baseline Characteristics of Participants

Cognitive Characteristics of Diabetes Self-Care: Self-Care Behavior

As described in Section 5.3.3 on the baseline characteristics of the participants, the participants were more likely to have received formal diabetes education and have better adherence to diabetes care than the general diabetes population (McCaul, Glasgow et al. 1987). On average, participants reported 'usually' following their diabetes treatment plan over the past 1-2 months. Thus, the participant population is not ideal

population to study the effect of a health technology on the change of frequency of the reported self-care behavior. Here the frequency of the reported self-care behavior was taken as a measure of their diabetes self-care. However it is an important population to study the effect of health technology on satisfaction and quality of life of people with diabetes. The effect of the Health-Zero orb on the quality of life of the participants can be judged based on their interpersonal and affective interaction with the system. This is further discussed in the next two sections.

The participants also reported a complete understanding of their recommended treatment plan for the different aspects of the diabetes management: glucose monitoring, exercise, medication, meal plan, medical appointments and treating lows. Thus, they perceived that they knew the correct self-care behavior to manage their diabetes and they did it in practice (high aggregate score on self-care inventory). In this scenario, the participants can consider the role of the Health-Zero orb to be of a reminder of their blood glucose levels rather than influence them in taking the correct actions. The Health-Zero orb will be more beneficial to them in domains other than the cognitive domain of observation (self-care behavior). This found to be the case was the case. A majority of the participants (seven of the eight participants) rated the Health-Zero orb being 'useful' or 'very useful' in helping them manage their diabetes. Six of the eight participants rated that the Health-Zero orb 'helped' remind them of their blood glucose levels. At the same time, they did not report the Health-Zero influencing them in other aspects of the diabetes regimen: meal plan, medication and exercise. The cases where the participants did report the Health-Zero orb to be influencing their meal plan, medication and exercise will be discussed separately when we consider the effect of the phase of diabetes of the participants on the self-care behavior.

Affective Characteristics of Diabetes Self-Care: Attitude towards Diabetes

The outcome of the study would be dependent on the phase of the diabetes that the participants were during the study. People with diabetes go through three distinct stages to cope with and manage their diabetes: denial, complacency and acceptance (RiteAid 2004). Each phase has its implications on diabetes care as it changes the psychological attitude of the person with diabetes. The denial phase refers to the first phase when people are diagnosed and they are in a state of shock and disbelief. They require information about the management of their diabetes. During the second phase of complacency, people try to establish a routine to manage their disease. This includes the process where people with diabetes make changes to their lifestyle to successfully cope with their diabetes. The third phase of acceptance relates to the acceptance of the reality of living with diabetes and being proactive about dealing with it through effective

habits. There are also later phases that are related to complications due to diabetes that are not discussed here.

Based on the baseline data of the date of diagnosis of diabetes of participants, three of eight participants (participants 1, 3 and 10) can be considered to be in the acceptance phase where they were proactive about the management of their diabetes and considered themselves in control. All of them had diabetes for at least 10 years. Their being in the acceptance phase was also corroborated by the personal interaction of the participants with the researcher where they expressed being 'in control' of their diabetes self-care. These participants are already in a routine for managing their diabetes and know what to do. Participant 12 was diagnosed with diabetes less than a year ago but reported maintaining excellent diabetes self-care and believed himself to be good at managing his diabetes. He too can be considered to be in the acceptance phase.

Participants 9 and 11 were diagnosed with diabetes less than a year ago and could be considered to be in the complacency phase where they are still trying to manage their diabetes and establish a routine. Participant 6 could be considered in the emotionally heavy phase due to the presence of complications from the disease. It was not clear whether participant 5 was in the complacency phase or the acceptance phase.

Participants in the acceptance phase can be hypothesized to find the Health-Zero orb less useful in the maintenance of their diabetes as compared to those in the complacency phase who are still trying to establish a routine. They should also report a less change in the aggregate self-care behavior as compared to participants in the other phases. This was indeed the case. Participants in the acceptance phase reported the Health-Zero being less useful in the management of their diabetes as compared to the other participants. They also reported a less change in the aggregate self-care behavior. The increase in the self-care behavior of participant 3 can be attributed to the fact that he was part of a diabetes camp that would increase his or her self-adherence.

Interpersonal characteristics of diabetes self-care: Support From Friends and Family

Little can be said about the baseline characteristics of the participants in terms of the support they received from their friends or family members towards the management of their diabetes. It is a limitation of the study that the questionnaire used for measuring social support was generic and measured the overall support received by the participants from friends, family members and a special person. As remarked by one of the participants, the measurement depended on his affective state on the day he as reporting the questionnaire and was not a good reflection of the support he receives from friend or family members. This situation is discussed elsewhere in detail in Section 5.62

Cognitive Interaction: System Usability

There were some design constraints in the Health-Zero system that significantly changed the dynamics of interaction between the system and the participants. The installation problems faced by the participants and the lack of the responsiveness of the system increased the user frustration with the device. Some of the comments provided by the participants indicated that the need to connect the glucose meter to Device 2 (Bluetooth transmitter) negatively affected their attitude towards the system.

This could significantly affect the use of the Health-Zero system and its effect on self-care behavior. It is difficult to determine the direction of the outcome. The participants were typical early adopters of technology. They would try harder to get the system to work and thus at times be more focused on their diabetes by checking blood sugar more often. One of the participants during the installation would check their blood sugar and call me to ask if the system was operational. In this process, he unintentionally increased his checking of the blood glucose levels. However, in the long term, system usability issues may reduce the use of the Health-Zero system by the participants. This may mean not taking the blood glucose level as often as they would have otherwise.

Seven of the eight study participants were individuals who spent a majority of their day outside their home. The only time during which they used the Health-Zero orb was in the morning and late at night. A major part of diabetes self-care happens during the day. The system was unavailable for use by the participants and this limited its potential to affect actual diabetes self-care behavior.

Uniform instructions were provided for use of the system to all the participants (Appendix H). As described in Section 5.51, the participants were instructed to place Device 2 (transmitter attached to the glucose meter) in the same room as the computer. This seriously limited the mobility of the system to a few feet. A serial cable directly connecting the glucose meter to the computer could have then performed an equivalent function with less cost and a simpler design. It is important that the system be able to function within the individual's home without the individual having to worry about the availability of the connection. Every time the participants had to take their blood glucose level, they needed to come to the room where they had their computer, detach the glucose meter from Device 2 (Bluetooth transmitter), take the blood glucose reading and attach the glucose meter back again to Device 2 (Bluetooth transmitter). This is a lot of effort and severely limits the number of times participants may be willing to do it. Initially the participants might check their blood glucose values often to see the color change on the Health-Zero orb but as the novelty of the Health-Zero orb reduces, it is possible

that they would reduce checking the blood sugar values. This was not the case as measured by the self-care inventory.

Cognitive Interaction: Lack of Personalization

Diabetes interventions are most effective when they provide tailor-made advice for individuals (Brown 1992; Roter, Hall et al. 1998). Here the system was not personalized to specific participants but uniform for everyone. The guidelines provided for interpreting the color on the orb were based on general blood glucose target values and not specific to a study participant or to the activity being done at the time of measurement of glucose. Based on an individual and whether the blood glucose is measured before a meal, after a meal or while doing a strenuous activity, the same blood glucose can be considered high, low or normal. In an ideal case, it is best to keep the blood glucose as close to the normal value of a person who does not have diabetes. However, many times it is not possible to do so based on the severity of the diabetes. In such a case it is important that the color be representative of whether the person has been able to maintain his blood glucose according to his condition rather than relative to a person who does not have diabetes. For example, the personal orb of Participant 5 always stayed red as her blood glucose levels was always high. These could possibly create a mechanism where the individual does not feel encouraged to change as the system will not change no matter what the participant does. The comment provided by her proves this point. In such a case, the effect may be more negative than positive.

“It reminded me of how poorly I manage my diabetes. It would always be red. Only once, once it was green. That too because I did not eat anything for the whole day. I would never be able to get out of it (the orb displaying the red color).”

Table 5-24 Comment by Participant that Depicts the Result of Lack of Personalization of the Health Zero Orb

Cognitive Interaction: System Delays

Diabetes interventions are most effective when they include on going reinforcement and specific advice for behavior change (Brown 1992; Roter, Hall et al. 1998). In the study, the Health-Zero orb used color as the medium of reinforcement. However, the time delay between the measurement of the blood glucose level and the change in color of the Health-Zero orb severely decreased the value of this reinforcement. This time delay has been mentioned in the subjective comments provided by the participants.

“Orb went out of sync occasionally.”

“The lag time between my (blood glucose level) test and the orb changing color was too long.”

“Perhaps work on closing the large gap of time between the time that one checks his/her blood sugar and the time that the orb changes color – This would definitely be of more impact.”

Table 5-25 Comment by Participants that Depicts Systems Delays in the Health-Zero System

Blood glucose levels are extremely time sensitive and they change as an individual changes his or her activities. They are different before a meal and after a meal. A meal typically lasts 30 minutes. If the color on the orb takes more than 30 minutes to change, then not only is the information wrong, it also may also negatively affect the participant. This would have also affected the usefulness of the Health-Zero orb as the participants may not pay full attention to the color on the Health-Zero orb if they knew the information is ‘stale’. One can hypothesize that this would also lead to a decrease in the self-care behavior of participants in aspects where a specific behavior in a short period can upset the blood glucose levels like eating the correct food portions. This effect was observed marginally where the participants reported a slight decline on their self-adherence to “eating the correct food portions”. This and other such behaviors are presented in table 5-26. The responses from participants 3 and 6 were not included to calculate the mean response as they were engaged in activities that impacted their self-care behavior drastically: one had shifted to an insulin pump while the other was part of a diabetes camp.

Question in the Self-Care Inventory	Mean of the response of the Participants at Baseline	Mean of the Response of the Participants at Follow Up
3. Look at blood glucose patterns	4.67	4.5
5. Take the correct dose of diabetes pills or insulin	4.83	5.00
6. Take diabetes pills or insulin at the right time	4.00	3.83
7. Eat the correct food portions	3.83	3.67
11. Treat low blood glucose with just the right amount of carbohydrate	3.83	3.5

Table 5-26 Mean Responses of the Participants to Some of the Self-Care Inventory Questionnaire

Study Limitations

The experiment was also not controlled for the impact of participation in the study on self-care behavior. Participants could have changed their behavior simply because participation – independent of the device – heightened their consciousness of the importance of good self-management.

The study was for only 15 days. It is difficult to observe a significant shift in the behavior that can be measured by questionnaires or perceived by an individual. There is also a significant literature on the importance of the instruments used to measure self-care. It is possible that the change in behavior being measured was at a level of granularity that is different from the changed behavior.

There was no specific behavior change advice given to the participants. In the absence of such diabetes education, it is up to the participants to figure out the possible mechanisms through which they can improve self-care. As was evident by the comments made by some of the participants, this was the case where they did show a change in behavior. However this also means that if the participants are not sure of what they are doing

wrong, it would be difficult for them to change behavior and this affect diabetes self-care as measured by the self-care inventory.

5.6.2 Interpersonal: Social Support & Analysis of Primary Hypothesis 1b

Technology can significantly alter the dynamics of the interaction between individuals. Hypothesis 1b focused on improvement in the inter-personal domain of the participants by creating a communication channel between them and their friend or family member. But two factors prevented the result from being conclusive: the limited number of participants who chose to give a second Health-Zero orb to a friend or family member and the decrease in the social support reported by the participants as measured by the social support questionnaire. There seems to be a contradiction with a marginal increase in the self-care behavior (participants 10 and 11) with a decline in the measured social support. An interview with the one of the participants provided an insight into this anomaly. It was remarked that the social support scale measures the overall social support provide by friends, family members or persons. The overall social support does not positively correlate with the support provided by friends or family members to the participants in helping them manage their diabetes. The response to the social support questionnaire changes according to the affective state of the participants at the time of response to the questionnaire. This questions the validity of using a general social support questionnaire for measuring the support provided by friends or family members to the participants in helping the participants manage their diabetes. Thus responses of the participants to the Device Usage Questionnaires and the interaction of the participants with the researcher is used as the basis of analysis. Two specific cases (participants 10 and 11) are discussed to comment on the hypothesis.

“I think so. My response to the questions (in the social support questionnaire) may change depending on my mood. The response may change depending on what is happening in my life, my interaction with friends.”

Table 5-27 Comment on Mood Affecting the Response to Questionnaire on Social Support

In the case of participant 10, the second Health-Zero orb was given to a friend who lived a few miles away while participant 11 had the Second Health-Zero orb co-located in the house itself and used by her children. Table 5-8 and 5-9 summarizes their responses of the two participants to the different questions related to the second Health-Zero orb.

In the case of participant 10, the second Health-Zero orb was given to a friend who lived a few miles away while participant 11 had the Second Health-Zero orb co-located in the house itself and used by her children.

Participant 10 reported that the second Health-Zero orb did increase the support he received from his friend towards the management of his diabetes. His most important concern in the management of diabetes was to enable the people around him to know if he was hypoglycemic, so the worsening of the condition could be prevented. The use of the Health-Zero orb was beneficial in this. According to the participant, his friend called him when the second Health-Zero orb turned blue to ensure that he is well. In spite of this, the social questionnaire showed a decline in the social support received from friends.

Participant 11 reported that the second Health-Zero orb was used by her children to ensure that she took care of her diabetes even if she was in a 'rush'. She reported an increase in the overall social support and also found the second Health-Zero orb influencing the behavior of her family members towards the management of her diabetes.

Both the situations emphasize that the Health-Zero orb was useful for the friend or family member in providing support to the participants in managing their diabetes, even if they reported a decline in the perceived overall social support. The decline is a reflection of their response on a particular day and the limitation of the instrument in measuring the social support provided to the participants by friend or family members in helping the participants manage their diabetes. Table 5-8 and 5-9 summarizes their responses of the two participants to the different questions related to the second Health-Zero orb.

5.6.3 Affective Interaction

Affective Domain: Attitude Towards Blood Glucose Levels

Self-care in a chronic disease is not just about actual behavior but also about the psychological attitude of an individual towards the disease. The participants liked using the device and felt that it was fun to use. Tables 5-28 and 5-29 summarize the response of the participants to the use of the personal Health-Zero orb and the use of a second Health-Zero orb by their friends or family members.

	Loved It	Liked It	No Opinion	Annoyed Me	Hated It
1. How did you feel about the orb?	■ ■	■ ■ ■ ■ ■ ■			
		■			
	Never	Rarely	Sometimes	Usually	Always
5. Was the orb fun to use?			■		■ ■ ■ ■ ■ ■
					■ ■

Table 5-28 Interpersonal Evaluation of the Friend or Family Member Orb for Participant 10 and Participant 11: Part II

1. How did your friend or family feel about their orb?	Loved It ■	Liked It ■ ■	No Opinion	Annoyed Me	Hated It
5. Do you feel the orb was fun to use by your friend or family?	Never	Rarely	Sometimes	Usually ■	Always ■ ■

Table 5-29 Interpersonal Evaluation of the Friend or Family Member Orb for Participant 10 and Participant 11: Part II

The Health-Zero orb did achieve something unique: it brought a feeling of fun in observing the blood glucose levels, not just for the participants but also their friends or family members. Most of the traditional healthcare devices are not fun to use. The personal interview with the participants gave the researcher a chance to analyze what made the Health-Zero orb fun. Some of these comments are provided in Table 5-30

“It (personal orb) is like a game. It gives you an incentive if you liked the color.”

“It (the family orb and the personal orb) became a game between me and my wife. One became her orb and one became mine. She would try to see which orb changed faster.” (both the orbs were located in the same home)

Table 5-30 Interpersonal Evaluation of the Friend or Family Member Orb for Participant 10 and Participant 11: Part II

Earlier works have explicitly used games to make an individual more aware of his or her physiological signals like extremity computing (Gerasimov 2003) and DiabetNet (DiabetNet, 2004). In Extremity Computing, games were used as a mechanism to present health information to adults and children. The games used the physiological signals as a feedback loop. In Diabetnet, computer games on a PDA were used to promote healthy glucose monitoring behavior among children. But there is a fundamental difference in the way the Health- Zero orb introduced the concept of games. When one is using the Health-Zero orb, the participants in the game are not pre-decided. Anyone who interacts the Health-Zero becomes a participant in the game like the visitors who would question about the personal Health-Zero orb. This also changes the interaction the visitor has with the person with diabetes.

Affective Domain: Stress Related to Chronic Disease Management

In the study, it was clear that the Health-zero orb changed the attitude of some of the participants from being directed towards maintenance of a specific number to maintaining a specific range. Table 5-31 lists some of the comments made by the participants.

When I take my blood sugar in the morning, I was always concerned about if it was 97 or 103. I wanted it to be below 100. But the color says you are OK. They are both green. Don't worry about it. I didn't worry about the number.

Numbers come and go. I could not tell you what my blood sugar was but I might remember if it was blue. Actually, I remember last morning it was yellow.

Color is Boolean. It is very easy to comprehend and you need not know the nuances of diabetes.

The number (blood glucose reading) is like a test score. You have to do well on it. Diabetes is a chronic disease. You see that number day in and day out. It burns you out. Anything that helps shift the focus is good. The color helped me shift the focus.

Table 5-31 Interpersonal Evaluation of the Friend or Family Member Orb for Participant 10 and Participant 11: Part II

How is this change reflected in actual behavior and whether it is beneficial or not requires further analysis. In the short term, one can hypothesize that there may be a possible negative consequences. Participants may err on the side of numbers that seem comfortable to them. Thus a participant may consider 90 (which represents a green) as being significantly better than 89 (which is blue). Now participants who see blue will be over cautious of their self-care behavior (if the use of the Health-Zero orb affects their self-care behavior) while participants who see green may tend to be under-cautious. For future system design, it will be useful to have the color represent a continuous variation in the blood glucose levels rather than represent a range.

Another important factor relates to stress. Can this tendency to be less focused on the maintenance of numbers decrease the stress associated with the management of diabetes? Will it tend to relax the users? What effect does reduction in stress related to diabetes have on diabetes self-care behavior?

Affective Domain: Strength of Color

Color has a strong affective response with each individual having its own preferences. The color creates a strong connection with the participant and depending on the choice of the color, this can have a positive or

negative effect on the behavior. Hence, the choice of the color in system design becomes important.

The choice of red, green and blue as the colors with green indicative of a normal blood glucose range and red and blue being high or low confirmed this. The cultural bias of the participants towards red as the 'pay attention' or 'danger' color was evident from their subjective responses. This significantly reduced the cognitive load on the participants to understand the meanings of the color.

However, improvements could have been made. Hypoglycemia or low blood sugar is considered a more dangerous medical condition as compared to high blood glucose levels. Thus it would have been more appropriate to have red represent 'low blood glucose levels'.

Another improvement could have been personalization: the use of favorite color to represent the blood glucose level. One participant who reduced her blood glucose to see her favorite color on the ambient device demonstrated the possibilities involved in allowing individuals to choose their preferred colors.

5.6.4 Technological Evaluation

The study removed the permanence of the environment: it transformed the environment according to the physiological state of the individual. This transformation is the first step towards enabling the environment to be an active participant in the health of an individual: active but not controlling.

The use of the ambient displays to represent the blood glucose level of the participants transformed the environment. This transformation was not just for the participants alone but anyone who shared the environment with them: their friends and family members. This transformation changed the interaction each of them had with the environment and with the participants. The same environment is shared and has different meanings to different individuals. The environment determines the context of the information, its use is determined by the individual. Each of them experienced the Health-Zero orb individually – personalized and yet collective. The next few sections explore the major aspects of these experiences.

Cognitive Domain: Interfaces

Interfaces need to be simple, if not completely eliminated. The Health-Zero ambient display system suffered from the design flaw of having multiple interfaces. Each of these interfaces created a potential point of problem and increased the complexity of the system. As was observed in the results, many installation and operational inconveniences resulted

from these interfaces: interface between the glucose meter and Device 2 (Bluetooth wireless transmitter) or the interface between Device 1 (Bluetooth wireless receiver) and the computer. The additional requirement of the home computer and a high speed internet connection potentially also prevented participation.

It was realized during the course of the development of the Health-Zero ambient display system that it may be possible for the glucose meter to directly communicate with the orb using the bandage-sized sensor board developed in the previous exploration. This required change in the study protocol and new approvals. In the interest of time, it was decided to continue with the development of existing system. The use of the sensor board would have removed the requirement of the home computer, the internet connection and the Health-Zero ambient orb network. This would have significantly reduced the complications and improved system usability.

Cognitive: Symmetry

There was an asymmetry of information flow between the participants and the Health-Zero ambient display system. In this case, the participants provided information about their state to the Health-Zero orb but they did not have access to the state of the system. Many of the participants highlighted this design flaw and wanted to know if their system was installed correctly and was operational. Existing mechanisms to inform the participants of the state of the system like, graphical windows had to be removed due to a bug in the Java Run Time environment. It also prevented the individual from having an effective interaction with the device.

Multiplicity of Experiences

An environment has different meanings to different individuals and every individual can derive different experiences from the same environment. The Health-Zero orb was similar. The same personal health-zero was useful for different members of the family for different reasons. A specific case might illustrate the point better. One of the Health-Zero orbs was used by a participant who had a young child. The orb for the participant was mechanism to remind himself of the blood glucose levels. But for the child, it served as a device to tell when daddy's sugar was low. For the participant the granularity of the information displayed was low: it was preferable to have a number on the display as well. But for the child it was right as the child did not know how to read numbers. It raises questions of how can we design a device that can serve multiple functions.

Spatial Distribution

An environment is distributed and connected. The participants wanted a similar experience from the Health-Zero orb. One of the participants wanted it to be connected to the ignition of his car so when he is hypoglycemic, he can be prevented from using the car. Another participant wanted to use the device both at his home and office. The third participant did not care about behavior change. All she wanted was someone to be able to control and influence her diet.

6 Conclusion

The contribution of the thesis is at two levels: Health-Zero and the individual explorations. I present the contributions to the field followed by the contributions of the individual explorations.

6.1 Health-Zero

I started with a vision of Health-Zero and towards this goal proposed the use of an integrated framework for healthcare for evaluating user experience with a new health technology. The model emphasized the consideration of the affective, cognitive, inter-personal and moral domains of observation in the design of a new health technology. The emphasis on these aspects was used in the design of the hardware for a miniaturized wireless network of body sensors (exploration A). The model was also used during system design and evaluation of exploration B.

6.2 Exploration A

I aimed to develop a network of wireless bandage-sized sensors for wearable health applications. As a building block for the network, I made a wireless sensor for measuring and communicating 3-lead ECG. The sensor used 2.4GHz communication frequency. It supported bi-directional communication and could connect with 125 other sensors at the same time. The system was built for economies of scale and the prototype cost of the sensor was only \$48.

6.3 Exploration B

I developed a new computer-based ambient blood glucose level visualization and feedback device and evaluated its effect on diabetes self-care. Here feedback relates to the communication of the blood glucose level to an individual as well as to a friend or family member. The device was the first of its kind to display the blood glucose levels of an individual as a color and to be able to automatically provide the same color value to a friend or family member of the individual with diabetes. It could wirelessly connect to a glucose meter using bluetooth and upload the latest readings.

The evaluation of the system demonstrated the value of having better mechanisms for visualization and communication of the blood glucose levels of diabetes and the strong affective nature of color for observing blood glucose levels. Results suggested that designing better blood glucose level visualization systems can help people better manage their diabetes. It may also help friends and family members of the person with

diabetes to better understand the blood glucose levels of the person with diabetes.

The study also demonstrated that such a system was perceived to be useful by the participants in helping them manage their diabetes. The participants related personal experiences of how their friends or family members who had a Health-Zero orb provided social support to help them manage their diabetes. It also highlighted the strong psychological component of self-care in diabetes that needs to be considered while designing devices for the visualization of blood glucose levels. However, the instrument used for measuring the social support did not show a corresponding increase. We learnt later that another questionnaire was more useful in measuring social support specific to diabetes self-care (Karen and Greca 2002; Greca and Bearman 2002) than the instrument of social support (Appendix G) used in the study.

The study was conducted with eight participants who were provided with a Health-Zero orb that could display their blood glucose levels as a color. Three of the eight participants gave a second Health-Zero orb to a friend or family member. The participants were measured for their self-care behavior at baseline and at follow up (end of 15 days of use of the Health-Zero orb) using the self-care inventory. They were asked to evaluate their use of the Health-Zero orb. There was a marginal increase in the self-care behavior of six of the eight participants. The participants also related individual experiences of the usefulness of the Health-Zero orb in reminding them of their blood glucose levels and in helping their friends and family members to understand their blood glucose levels. The visualization of blood glucose levels as a color was reported as less stressful than using a number for the representation of the blood glucose level. As a strong behavior measure for the evaluation of the system, all the participants liked using the Health-Zero orb and felt it was fun to use. They also wanted to use the system again provided the portability of the system was improved. This study has shown that effective use of technology to design devices for diabetes can have an impact on the self-care behavior of people with diabetes and potentially increase the support provided by their friend or family members in helping them manage their diabetes. Another contribution was that it brought a feeling of fun in observing the blood glucose levels, not just for the participants but also their friends or family members.

7 Future Work

7.1 Health-Zero

In this thesis, I was able to demonstrate the feasibility and the importance of using technology to create health systems that focus on the interaction with the whole individual. An important future contribution can be to provide an economic justification for Health-Zero and determine how the same principles can be use to create products.

7.2 Exploration A

The first exploration opens further research areas specifically in the technical design of the ECG sensor, the product design and the use of the sensor towards creating a community of health sensors.

The technical design of the ECG sensor could be improved in various ways. The board can be further miniaturized by using smaller components and multi-layered boards. In the thesis, the need for hand-assembly of the board limited the minimum size of the components used. As was mentioned in section 4.4.2, smaller capacitors reduce inductance and thus are a better choice for making the board. The board was a simple two-layered board. One can fabricate a multi-layered board with tighter margins between the vias. This would also increase performance. A primary reason for not doing in the thesis was the cost of production. Large volume production of multi-layered boards would cost a lot less as compared to building an individual prototype. The above steps improve performance as well as user comfort. This would increase user comfort. The quality of the ECG signal can be further improved by using shielded cables and filters to remove the low frequency power harmonics present in the system. The interference from 60 Hz power harmonics was a major noise component that was present in the ECG signal.

The goal of the exploration was to create a product: a cheap, easy to use physiological sensor. Towards this goal, it would be important to work towards packaging the sensor more effectively. The form of the sensor can be changed. The substrate used for the board was the standard material available FR-04 1 oz copper board. Flexible substrates are available and can be a future material for the manufacturing of the board. The electrodes instead of having leads could be directly placed on the bandage itself.

The wireless bandage-sized sensor was developed to be a building block for creating a community of health sensors. The single sensor developed can be reused to create different bandage-sized sensors. The sensors could be combined with an existing wearable system. For example it could be

used to enhance MITHril (DeVaul, 2003), a wearable system that uses a PDA as the base station. The sensors can be a rich source of information while the PDA would be a good base station for computation and data analysis. Possible applications of such a system could be long-term health behavior monitoring.

7.3 Exploration B

The second exploration opens areas of research in the engineering design of a new Health-Zero diabetes orb system and research studies. The Health-Zero Orb study showed promising results for the effect of an ambient blood glucose level visualization system and feedback device on diabetes self-care. However, the study was on a small set of people with diabetes for a short time-period. It was contained to a very specific population: early adopters of technology and those who usually followed their diabetes treatment plan. Due to this, the room for improvement in the change in the frequency of the self-care behavior was low. However, the study showed that there is a change in the quality of life associated with diabetes with the participants reporting that it was fun to the Health-Zero orb, a diabetes health device. The initial goal of the exploration was to improve self-care behavior. The improvement in the quality of life of people with chronic diseases like diabetes is important. A new study could potentially focus on this aspect of wellness. One can also do a longer follow up study with a population size that will be sufficient to statistically substantiate the results.

Another area of exploration could be the expansion of the study to people with diabetes who generally do not follow their diabetes treatment plan and see if there is improvement in the frequency of their self-care behavior. A study could also focus on the majority of technology users as compared to the early adopters.

The Health-Zero system was found useful on average by the participants. However, there were problems in the usability and mobility of the system. Another path for further exploration could be the development of a more portable system. A wireless glucose meter could be developed where the Bluetooth connection is inbuilt into the glucose meter. It is possible to directly connect a Bluetooth chip to the LifeScan Ultra glucose meter without the interface cable and have the transmitter powered by the glucose meter. The color transition in the existing Health-Zero system was abrupt. One can work on designing a system where the color transition is gradual so it reflects a continuity of the blood glucose values. One can also use a cellular network to relay the blood glucose levels than the ambient device network used for the study.

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9 Appendices

Appendix A: Bill of Materials for ECG Sensor

Appendix B: Schematics for ECG Sensor

Appendix C: Study System Documents

Appendix D: Study Recruitment Materials

Appendix E: Study Screening Documents

Appendix F: Study Consent Forms

Appendix G: Study Instruments

Appendix H: Study Installation Instructions

Appendix I: Interpretation Sheets

Appendix J: Study Response to Questionnaires

Appendix K: Clinical Information for Diabetes

Appendix L: Clinical Information for ECG

Appendix M: Glossary

Appendix A: Bill of Materials for ECG Sensor

The appendice provides the bill of materials for the ECG Sensor. The total cost of the parts was \$26. The fabrication cost of the board was \$24.

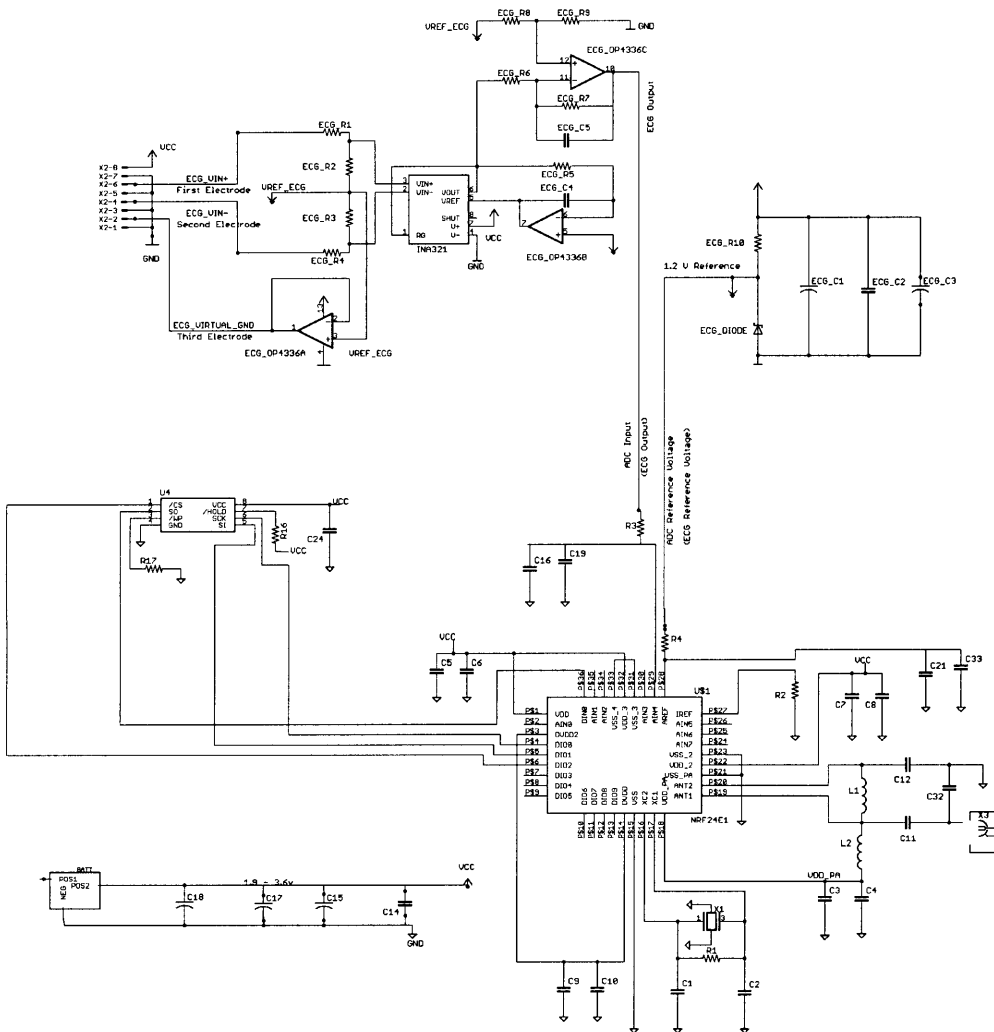
BOM for ECG1 Bandage-Sized ECG Sensor

Designator	Part Type	Footprint	Description	Vendor	Distributor	Part Number	Price	Website
C1	15pF	603	CAP CERAMIC 15PF 50V NPO 0603	BC Components	DigiKey	BC1227CT-ND	0.55	www.digikey.com
C2	15pF	603	CAP CERAMIC 15PF 50V NPO 0603	BC Components	DigiKey	BC1227CT-ND	0.55	www.digikey.com
C3	22nF	603	CAP CERAMIC 15PF 50V NPO 0603	BC Components	DigiKey	BC1227CT-ND	0.55	www.digikey.com
C4	22pF	603	CAP CERAMIC 22PF 50V NPO 0603	BC Components	DigiKey	BC1229CT-ND	0.0325	www.digikey.com
C5	1nF	603	CAP CERAMIC 1000PF 50V CERAMIC X7R 0603	BC Components	DigiKey	BC1227CT-ND	0.055	www.digikey.com
C6	10nF	603	CAP 1000PF 50V CERAMIC X7R 0603	BC Components	DigiKey	BC1252CT-ND	0.0325	www.digikey.com
C7	10nF	603	CAP 1000PF 50V CERAMIC X7R 0603	BC Components	DigiKey	BC1252CT-ND	0.0325	www.digikey.com
C8	1nF	603	CAP 1000PF 50V CERAMIC X7R 0603	BC Components	DigiKey	BC1247CT-ND	0.0351	www.digikey.com
C9	1nF	603	CAP 1000PF 50V CERAMIC X7R 0603	BC Components	DigiKey	BC1247CT-ND	0.0351	www.digikey.com
C10	33nF	603	CAP 3300PF 25V CERAM X7R 0603	Panasonic ECG	DigiKey	PC01769CT-ND	0.088	www.digikey.com
C11	10pF	603	CAP CERAMIC 10PF 50V NPO 0603	BC Components	DigiKey	BC1223CT-ND	0.0351	www.digikey.com
C12	10pF	603	CAP CERAMIC 10PF 50V NPO 0603	BC Components	DigiKey	BC1223CT-ND	0.0351	www.digikey.com
C14	100nF	603	CAP 100 25V CERAMIC X7R 0603	Kemet	DigiKey	399-1283-1-ND	0.1911	www.digikey.com
C15	10 uF/6V	C3216	CAPACITOR TANT 10UF 6.3V 20% SMD	Kemet	DigiKey	399-1552-1-ND	0.167	www.digikey.com
C16	1nF	603	CAP 1000PF 50V CERAMIC X7R 0603	BC Components	DigiKey	BC1247CT-ND	0.0351	www.digikey.com
C17	4.7uF/6V	C3216	CAPACITOR TANT 4.7UF 10V 20% SMD	Kemet	DigiKey	399-1562-1-ND	0.153	www.digikey.com
C18	1uF/20V	C3216	CAPACITOR TANT 1.0UF 20V 10% SMD	Kemet	DigiKey	399-1609-1-ND	0.1338	www.digikey.com
C19	100nF	603	CAP 100 25V CERAMIC X7R 0603	Kemet	DigiKey	399-1283-1-ND	0.1911	www.digikey.com
C21	1nF	603	CAP 1000PF 50V CERAMIC X7R 0603	BC Components	DigiKey	BC1247CT-ND	0.0351	www.digikey.com
C24	10nF	603	CAP 1000PF 50V CERAMIC X7R 0603	BC Components	DigiKey	BC1252CT-ND	0.0325	www.digikey.com
C32	1.5pF	603	CAP CERAMIC 1.5PF 50V NPO 0603	BC Components	DigiKey	BC1224CT-ND	0.062	www.digikey.com
C33	100nF	603	CAP 100 25V CERAMIC X7R 0603	Kemet	DigiKey	399-1283-1-ND	0.1911	www.digikey.com
ECG_C1	10nF	C0603	CAP 1000PF 50V CERAMIC X7R 0603	BC Components	DigiKey	BC1252CT-ND	0.0325	www.digikey.com
ECG_C2	0.1uF	603	CAP 100 25V CERAMIC X7R 0603	Kemet	DigiKey	399-1283-1-ND	0.1911	www.digikey.com
ECG_C3	10nF	C0603	CAP 1000PF 50V CERAMIC X7R 0603	BC Components	DigiKey	BC1252CT-ND	0.0325	www.digikey.com
ECG_C4	0.1uF	603	CAP 100 25V CERAMIC X7R 0603	Kemet	DigiKey	399-1283-1-ND	0.1911	www.digikey.com
ECG_C5	1.6nF	603	CAP CER 1600PF 50V 5% COG 0603	Murata Electronics	DigiKey	490-1456-1-ND	0.13	www.digikey.com
R1	1M	603	RES 1.00M OHM 1/10W 1% 0603 SMD	Yageo America	DigiKey	311-1.00MHCT-ND	0.0238	www.digikey.com
R2	22K	603	RES 22.0K OHM 1/10W 1% 0603 SMD	Yageo America	DigiKey	311-22.0KHCT-ND	0.0238	www.digikey.com
R3	1K	603	RES 1.0K OHM 1/10W 5% 0603 SMD	Panasonic ECG	DigiKey	P1.0KGCT-ND	0.02465	www.digikey.com
R4	1K	603	RES 1.0K OHM 1/10W 5% 0603 SMD	Panasonic ECG	DigiKey	P1.0KGCT-ND	0.02465	www.digikey.com
R16	10K	603	RES 10.0K OHM 1/10W 1% 0603 SMD	Yageo America	DigiKey	311-10.0KHCT-ND	0.0238	www.digikey.com
R17	100K	603	RES 100K OHM 1/10W 1% 0603 SMD	Yageo America	DigiKey	311-100KHCT-ND	0.0238	www.digikey.com
ECG_R1	100K	R0603	RES 100K OHM 1/10W 1% 0603 SMD	Yageo America	DigiKey	311-100KHCT-ND	0.0238	www.digikey.com
ECG_R2	2M	603	RES 2.00M OHM 1/10W 1% 0603 SMD	Yageo America	DigiKey	311-2.00MHCT-ND	0.0238	www.digikey.com
ECG_R3	2M	603	RES 2.00M OHM 1/10W 1% 0603 SMD	Yageo America	DigiKey	311-2.00MHCT-ND	0.0238	www.digikey.com
ECG_R4	100K	603	RES 100K OHM 1/10W 1% 0603 SMD	Yageo America	DigiKey	311-100KHCT-ND	0.0238	www.digikey.com
ECG_R5	1M	603	RES 1.00M OHM 1/10W 1% 0603 SMD	Yageo America	DigiKey	311-1.00MHCT-ND	0.0238	www.digikey.com
ECG_R6	22K	603	RES 22.0K OHM 1/10W 1% 0603 SMD	Yageo America	DigiKey	311-22.0KHCT-ND	0.0238	www.digikey.com
ECG_R7	1M	603	RES 1.00M OHM 1/10W 1% 0603 SMD	Yageo America	DigiKey	311-1.00MHCT-ND	0.0238	www.digikey.com
ECG_R8	22K	603	RES 22.0K OHM 1/10W 1% 0603 SMD	Yageo America	DigiKey	311-22.0KHCT-ND	0.0238	www.digikey.com
ECG_R9	1M	603	RES 1.00M OHM 1/10W 1% 0603 SMD	Yageo America	DigiKey	311-1.00MHCT-ND	0.0238	www.digikey.com
ECG_R10	47K	R0603	RES 47.0K OHM 1/10W 1% 0603 SMD	Yageo America	DigiKey	311-47.0KHCT-ND	0.0414	www.digikey.com
L1	3.9nH	603	INDUCTOR CHIP 3.9NH +/-0.3NH 060	J W Miller Magnetics	DigiKey	M1246CT-ND	0.518	www.digikey.com
L2	22nH	603	INDUCTOR CHIP 22NH 5% 0603 SMD	J W Miller Magnetics	DigiKey	M1241CT-ND	0.518	www.digikey.com
X1	16MHz	ACT321SMX	TSX-10A 16 Mhz Oscillator	Toyocom	DigiKey	(TN4-25820)		www.northeastrep.com
X2	53261-08	53261-08	CONN HEADER 8POS 1.25MM R/A TIN	Hirose Electronic Co Ltd	DigiKey	H2206-ND	0.74	www.digikey.com
X3	Female SMA Connector	BU-SMA-V	CONN JACK BULKHEAD PCB 281" GOLD	Johnson Components	DigiKey	J494-ND	5.91	www.digikey.com
BATT	12mm Con Batt Holder	CONN-12MM	HOLDER BATTERY COIN 12MM DIA SMD	Keystone Electronics	DigiKey	3000K-ND	0.253	www.digikey.com

ECG_DIODE	LM385 1.2V Ref Diode	SO8	IC VOLT REF DIODE 1.2V 8-SOIC	National Semiconductor	DigiKey	LM385BM-1.2-ND	1.01	www.digikey.com
ECG_OP4336	SSOP16BU	bur-brown	IC QUAD MICRO PWR OPAMP 16-SSOP	Burr-Brown	DigiKey	OPA4336EACT-ND	3.71	www.digikey.com
U\$1	nRF24E1	QFN36	2401 Nordic 2.4 GHz transceiver	Nordic VLSI	Symmetry Electronics	nRF24E1	5.2	www.symmetryelectronics.com
U4	25AA320	SO-08	IC SERIAL EEPROM 32K 2.5V 8-SOIC	Microchip Technology	DigiKey	25AA320-I/SN-ND	1.08	www.digikey.com
ECG_INA321	INA321	SO8	IC R-R CMOS INSTR AMP 8-MSOP	Texas Instruments	DigiKey	INA321ECT-ND	3.11	www.digikey.com

Appendix B: Schematics & PCB Layout for ECG Sensor

Natalia Marmasse collaborated in the development of the schematic for the Nordic chip.



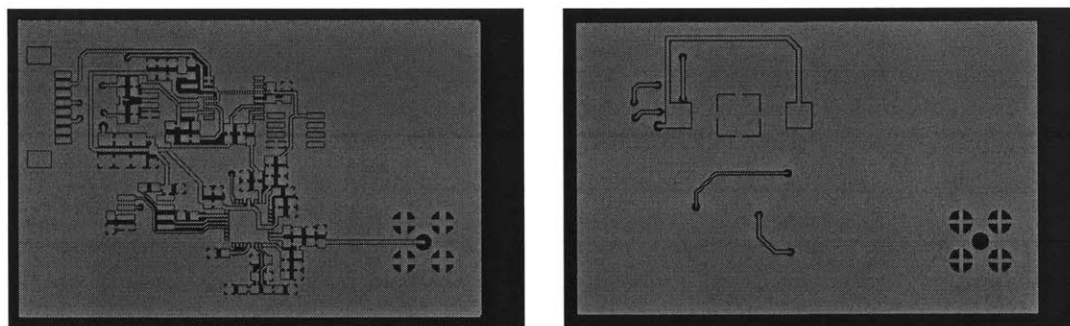


Figure B-2 Top (left) and Bottom (right) PCB Layer of the ECG Sensor

Appendix C: Study System Documents

These documents describe the construction and operation of the Health-Zero Diabetes System. The system was used as part of the Joslin Diabetes Orb Study explained in Chapter 5.

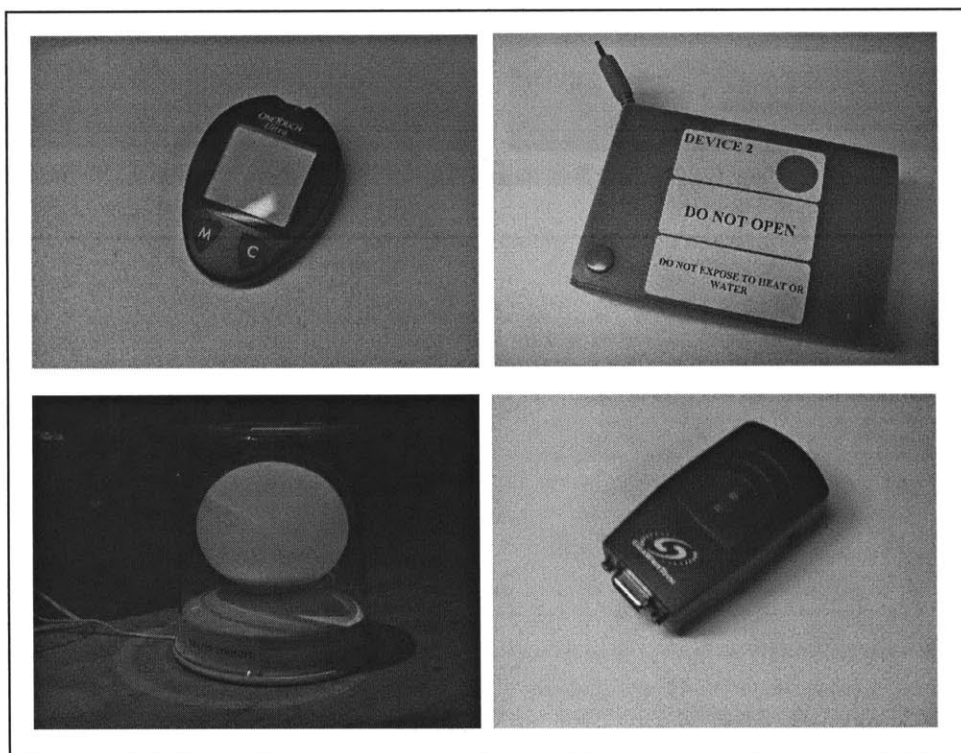


Figure C-1 The Health-Zero Ambient Display System (clockwise from top left: glucose meter, Device 2, Device 1 and Health-Zero Ambient Orb)

C1 System Synopsis

The system (figure C-1) enabled a glucose meter to wirelessly connect to the Health-Zero Ambient Orb through the study participant's home computer. It consisted of a glucose meter, Device 2 (Bluetooth Transmitter) with its one end inserted into the glucose meter, Device 1 (Bluetooth Receiver) that was attached to the home computer, the Health-Zero ambient orb and client software on the home computer.

C2 System Usage

The use of the system involved installation of the client software on the participant's home computer and use of the provided glucose meter to check blood glucose level. Device 1 was to be inserted into the bottom of the glucose meter and Device 2 was to be plugged into the serial port of the home computer. The Health-Zero orb was to be placed at a location where it is easily observable by the participants or the friend or family member of the participants, depending on its use. For the system to work, the glucose

meter needed to be connected to Device 1 and be in proximity (within 30 feet) of the computer. Constant internet connectivity was required and the Health-Zero orb needed to be in range of the ambient device network.

C3 System Detailed Description

Table c-1 provides the hardware components required for the functioning of the Health-Zero Diabetes Orb System. The components are listed in the order of data flow. In the next paragraph, each of the components is described in detail. Figure C-2 gives the signal flow in the system

Component	Specifications	Function
Glucose Meter	Johnson and Johnson One Touch Ultra®	Used for checking the blood glucose level of the participant
Device 1	Bluetooth Transmitter Module (Custom Built in collaboration with GigaWave Tech)	Used to transmit the blood glucose level from the serial port of the glucose meter to the participants' home computer
Device 2	Bluetooth Receiver Module (Custom Built in collaboration with Gigawave Tech)	Used to receive the blood glucose level on the serial port of the participants' home computer
Home Computer	Provided by the participants	Used to install the firmware to manage data flow of the blood glucose levels
Health-Zero Ambient Orb Network	Ambient Devices Ambient Network	Responsible for changing the color of the Health-Zero ambient orb once it receives a request from the Home Computer
Health-Zero Ambient Orb	Ambient Devices Stock Orb enclosed in plastic container	The Color was display on the orb and it represented a blood glucose range (See Appendix I)

Table C-1 Components of the Health-Zero Diabetes Orb System

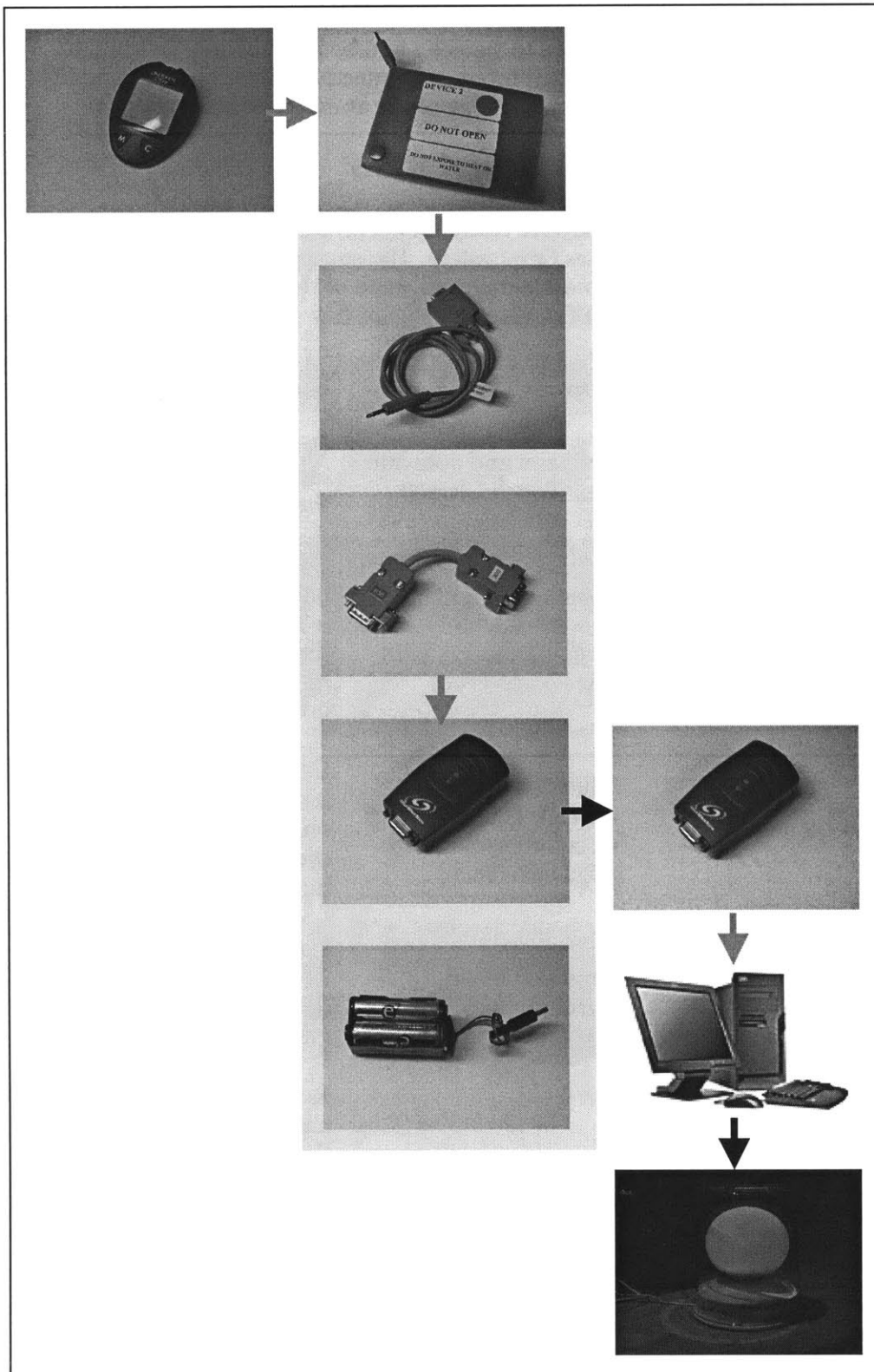


Figure C-2 The Complete Health-Zero Diabetes System according to the signal flow (black arrows indicate a wireless connection while grey arrows indicate a wired connection) (the shaded box are the components inside the casing of Device 2)

C3.1 Glucose Meter

The glucose meter used was Johnson and Johnson One Touch Ultra Glucose Meter. The glucose meter and the associated equipment (test strips and serial interface cable) were provided by Johnson and Johnson free of cost for the study. The measurement procedure involved inserting a One-Touch test-strip into the meter and using a lancet for penetration into the skin to obtain a blood sample. The blood sample was transferred to the meter. After approximately 5 seconds, the blood glucose level was displayed as a number on the screen. The meter was capable of storing its 150 most recent readings.

The blood glucose levels could be downloaded from the meter through the serial port of the computer using the LifeScan serial interface cable. The settings required were baud rate rate: 9600 bps, data bit: 8, stop bit: 1, parity: none and flow control: none. Detailed communication specification can be obtained from LifeScan (LifeScan 2004). HyperTerminal was used by the researcher debugging the flow control of the glucose meter. The command used was *DMP* to upload the glucose readings present in the memory of the meter. The use of the command involved sending three characters 'D', 'M' and 'P'. It was important that there be a specific delay between each of the characters which was of the order of 100 milliseconds. If the delay between each character was less than 10 milliseconds or more than 1 second, the meter will not respond to the command even at the baud rate of 9600 bps. It took some time for the researcher to figure this out.

C3.2 Device 1 and Device 2

Device 1 and Device 2 were used to establish a Bluetooth connection between the glucose meter and the home computer of the participants. They were developed through GigaWaveTech (Pte) Ltd, an independent wireless design house based in Singapore. GigaWave Tech manufactures Bluetooth Serial Port Dongles for cable replacement. These were modified by the company to meet the power requirements of the Health-Zero Diabetes Orb System.

Device 2, the Bluetooth transmitter module as shown in Figure C-1 was a rectangular box that contained a LifeScan serial interface cable connected to the GigaWaveTech Bluetooth Serial Port Dongle using a custom male-to-male serial connector. These different components present inside the rectangular casing of Device 2 have been shown in figure C-3. The GigaWaveTech Bluetooth Serial Port Dongle was powered by 4 AA non-rechargeable alkaline batteries. The pin connection of the male-to-male serial connector has been shown in table C-2.

The batteries used were high-density Energizer X91 AA batteries. They had a rating of 2500 mAh which ensured that they last for at least 15 days (they actually lasted for more than 30 days).

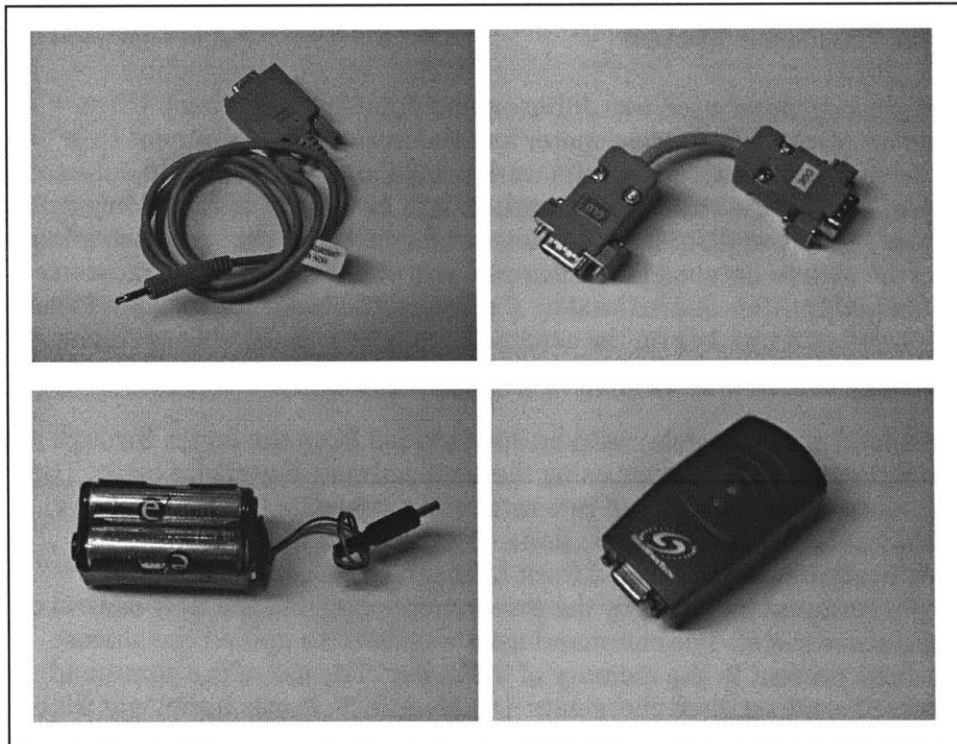


Figure C-2 Components of Device 2 (clockwise from top left: LifeScan Interface Cable, Male-to-Male Connector, GigawaveTech Transmitter, Battery Pack for Power)

Device 1, the Bluetooth receiver module was the GigaWaveTech Bluetooth Serial Port Dongle. It was powered through a 4.5 V power adapter.

Device 2 was the Bluetooth slave unit and Device 1 was the Bluetooth master unit. The slave was in sleep mode most of the times. For 11 milliseconds out of every 1.2 seconds interval, it would be turned on to sniff for any incoming requests from the master.

Signal Name (Male End)	Male Connector Connected to the Serial Port Dongle (Pin Numbers)	Male Connector Connected to the LifeScan Serial Interface Cable (Pin Numbers)
Transmit Data	2	3
Receive Data	3	2
DTR, DSR Loopback	4,6	4
RTS, CTS Loopback	7,8	Not Connected
Signal Ground	5	5

Table c-2 Signal Connection Between the Male-to-Male Connector

C3.4 Client Software

The client software was written in Java and was to be installed on participants home computer. It continuously tried to establish a bluetooth

wireless connection between the glucose meter and the home computer. If successful, it uploaded the most recent blood glucose value to the home computer. It then converted the blood glucose value to a color value and an animation value. The color value was based on the blood glucose level and has been described in Appendix I. The animation value was based on the time stamp of the latest blood glucose reading. If the last reading of the participant was at least six hours old, the orb was also made to blink at the same time. The color value, animation value and the Health-Zero Orb Device ID was then transmitted to the Ambient Device network to signal the orb to change its color. If the client software was successful in establishing a connection with the glucose meter, it waited for 20 minutes before a new attempt was made to establish the connection. A technical report provides the complete code of the software.

C3.5 Health-Zero Ambient Orb

The Health-Zero Ambient Orb used was the Ambient Devices Stock Orb. The orbs were loaned to us by Ambient Devices free of cost for the study. It was enclosed in an unbreakable kitchen plastic container to ensure the participants' safety in case the glass of the orb breaks. The orb retained its color until a new color value was transmitted to it

Appendix D: Study Recruitment Materials

This appendix provides the different recruitment brochures used for recruitment for the Health-Zero Diabetes Orb Study.

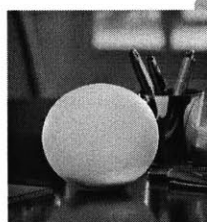
Figure D-1 gives the brochure that was displayed on the LCD screens present at the Joslin Diabetes Center at various places.

Figure D-2 gives the recruitment brochure that was present at the Joslin Diabetes Center and also mailed to the Joslin Clinic Population with the recruitment letter. The brochures were printed in black and white.

Figure D-3 gives the wall poster used for recruitment and displayed on the notice boards at the Joslin Diabetes Center.

The most effective recruitment strategy was the recruitment table where the Joslin Clinic Population was able to see the Health-Zero Orb.

RESEARCH OPPORTUNITY: **The Diabetes Orb Study**



**Explore new ways to visualize
blood glucose levels**

**Call (617) 732-2699 x4777 or email
akshay.mohan@joslin.harvard.edu
See brochures in the Clinic**

Figure D-1 Advertisement for LCD Screens at the Joslin Diabetes Center

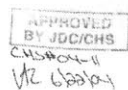
you may qualify if you ..

- ✓ have type 1 or type 2 diabetes
- ✓ are 18 years or older
- ✓ have no major visual impairment
- ✓ have a computer
- ✓ have a high speed internet connection

to find out if you are eligible, please call

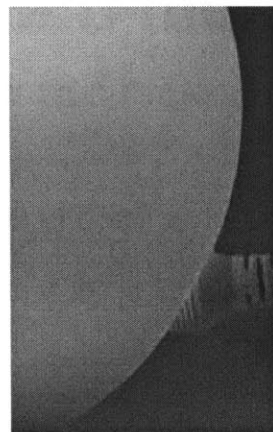
Akshay Mohan
at (617) 732-2699 x4777
akshay.mohan@joslin.harvard.edu

Behavioral Research
One Joslin Place
Room 350
Boston, MA 02215



Behavioral Research
One Joslin Place, Room 350
Boston, MA 02215

a research project at
Joslin Diabetes Center



The Diabetes Orb Study

exploring new ways
to visualize blood
glucose levels

help us answer an important question

the study is testing a multi-colored
display to see if it can help people
better manage their diabetes

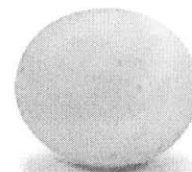
Participants will complete a set of surveys
before and after the study.

Participants will use a multi-colored display for
two weeks to indicate their blood glucose level.

Participants may give a second display device
to a friend or a family member

Participants should come to the Joslin Diabetes
Center for two study related visits.

participants receive :



- a chance to use the display device shown above
- a free blood glucose meter
- free test strips for 15 days
- monetary compensation
- free parking

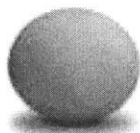
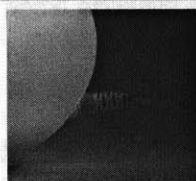
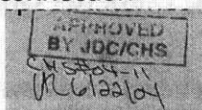
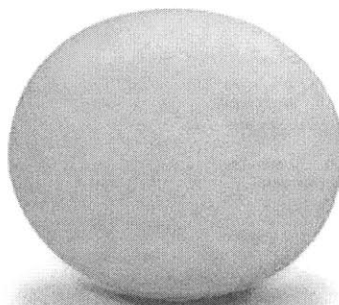
Figure D-2 Recruitment Brochure

Join the Diabetes Orb Study

exploring new ways to visualize blood glucose levels

you qualify if you

- ✓ have type 1 or type 2 diabetes
- ✓ are 18 years or older
- ✓ have no major visual impairment
- ✓ have a computer
- ✓ have a high speed internet connection



Receive free blood glucose meter, test strips, parking and monetary compensation

Use a multi-colored display for two weeks to indicate your blood glucose level

You may give a second display device to a friend or family member

Come for two study related visits to the Joslin Diabetes Center and complete a set of questionnaires

Akshay Mohan
Diabetes Orb Study
617-732-2400 x4777
akshay.mohan@joslin.
harvard.edu

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Diabetes Orb Study
617-732-2400 x4777
akshay.mohan@joslin.
harvard.edu

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akshay.mohan@joslin.
harvard.edu

Akshay Mohan
Diabetes Orb Study
617-732-2400 x4777
akshay.mohan@joslin.
harvard.edu

Figure D-3 Wall Brochure

Appendix E: Study Screening Documents

The Diabetes Orb Study Telephone Screening Form

Type 1 ☐

Type 2 ☐

1. Name: _____ MR# _____

2. Sex: Male ☐ Female ☐

3. Do you have any major visual impairment or color blindness?

4. Do you have a computer?

5. Do you have a high-speed internet connection?

6. Phone numbers: Day _____ Evening _____

7. How did you hear about the study? _____

8. Age: _____ →

☐ older than 75
☐ type 1 younger than 18 ☐ type 2 younger than 25

9. Date of Birth: ____ / ____ / ____
 mm / dd / yyyy

10. When were you diagnosed with diabetes? _____ →

☐ less than 2 years

11. Are you currently in any other research studies? ☐ no
 if yes: what study? _____ (this may or may not exclude them)

12. Address: _____ Email (if desired): _____

13. Where do you receive your primary diabetes care? _____

14. Are you a patient at Joslin Diabetes Center? ☐ no ☐ yes

Comments: _____

Appendix F: Study Consent Forms

The two documents: study consent form and the HIPAA document was to be signed by the study participant before he or she could begin the study. Two copies were made of the consent form with one copy provided to the study participant and the other to the Joslin Office of Sponsored Research.

Form Revised December 2000

CHS #: 04-11
Date: 5/18/04

Committee on Human Studies

Informed Consent Form

Subject's Name: _____

Subject Status: Patient _____ Volunteer _____ Employee _____

Principal Investigator: Katie Weinger, Ed. D.

Co-Investigator(s): Akshay Mohan, B.Tech

Project Title: Effective Feedback and Visualization Tools for Diabetes

This Portion To Be Reviewed and Signed by Subject:

This consent form may contain words that I do not understand. I will ask the study physician or a member of the staff to explain any words or information that I do not understand.

PURPOSE OF PROJECT:

The purpose of the study is to test a computer and light display system called Health-Zero that may help with diabetes self-management for adults with type 1 or type 2 diabetes by showing when the blood glucose readings are too high, acceptable or too low. The Health-Zero display device shows blood glucose readings as a color whenever a blood glucose level is measured with a blood glucose monitor.

This study will involve 12 subjects with diabetes and is being done at the Joslin Diabetes Center as part of a thesis project at the Massachusetts Institute of Technology (MIT).

VOLUNTARY:

My participation in this study is voluntary. I may refuse to participate or even withdraw after the study has started. In either case, I will not be penalized or lose any benefits to which I am otherwise entitled. The study staff or the study sponsor may stop my participation if the study device is not working, if I do not follow the study schedule, or if there is a change in my medical condition.

My decision to participate or not to participate in this study will not affect my current or future healthcare or other benefits I receive at the Joslin Diabetes Center.

1

I do not have to make any changes to the steps I take for measuring my blood glucose level or to my normal routine for managing my diabetes for this study.

Every time I take my blood glucose level with the blood glucose monitor for the study, the blood glucose value will be wirelessly transmitted from my glucose meter to my home computer. The computer program that I have installed will use this blood glucose value and convert it to a color value. This color value will then be transmitted to my Health-Zero display device that will change color according to the level. The color on my display device will remain there until I check my blood glucose level again. This can help to remind myself of my blood glucose value that I took last.

If my friend or family member is also involved in the study, the display device I have given to my family member will also display the same color as my display device and will provide him information about my current blood glucose level.

This study will not interfere or require me to make changes to my medical care. Any changes that need to be made in the medical management of my diabetes care will be made as usual by my existing diabetes team and should not be based on the color value of the Health-Zero display device since, the color on the display device is to be used solely as an indicator of my blood glucose level.

Visit 2

After checking my blood sugar levels for about 15 days with the blood glucose monitor provided by the study and the Health-Zero display device, I will return to the Joslin Diabetes Center.

At this visit, I will complete another set of surveys that will include questions about my diabetes management and my use of the Health-Zero display device. If my friend or family member was also involved in the study, I will fill an additional survey about the reaction my friend or family member had to the device. I can also share any stories related to the use of the display device. These surveys will take approximately 30-40 minutes to complete.

At this visit, I will bring all the devices provided for the study including the glucose monitor I used for taking my blood glucose level. The memory of my glucose monitor will be downloaded to a password-protected computer located at the Joslin Diabetes Center. Only the study coordinator will review this information. All information will be kept confidential and my name will not accompany the data. I have the option of keeping this glucose monitor once the memory has been downloaded.

RISKS AND/OR DISCOMFORT:

Participation in testing the study device involves minimal risk to me. However, participation in any research bears some risks, inconveniences, or even some risks that are not expected.

Using the Study Devices

I may feel inconvenienced by the need to install the Health-Zero display device and the computer program on my home computer. I may also be inconvenienced by needing to measure my blood glucose at least four times a day using the glucose monitor provided to me. There is no risk to me if the Health-Zero display device has technical failure since I can return to my usual method of tracking my blood glucose value at any time.

Sharing Blood Glucose Levels with Others

I understand that I may be uncomfortable in sharing my blood glucose level with my friends or family members.

Important Information

If I have any questions about the study or if an adverse event or research related injury occurs as a direct result of my taking part in this study, I should immediately contact one of the study investigators: Akshay Mohan at (978) 423-9069 or Katie Weinger at (617) 732-2488.

I also understand that it is not the policy of the Joslin Diabetes Center or MIT to provide free medical treatment or financial compensation for such things as lost wages, disability, and discomfort as a result of such event or injury.

BENEFITS:

There is no guarantee that I will benefit by participating in this study. However I may benefit through increased diabetes self-care. If the Health-Zero is useful, people with diabetes may benefit from this research.

COST/PAYMENT:

I will receive \$10 for each study visit I make to the Joslin Diabetes Center. If I complete the study, I will receive a total compensation of \$20. I will receive free parking for all study related visits. I will have to return all the devices provided to me for the study. However I will have the option of keeping the glucose monitor provided for the study after its memory has been downloaded.

CONFIDENTIALITY:

I understand that medical data collected from my participation in the study will be subject to the Joslin Research Confidential Information Policy and will not be revealed or disclosed to anyone other than the members of the study staff and will be made available to the FDA (Food and Drug Administration) and other regulatory agencies upon request. However there is a risk of breach of confidentiality that cannot be totally eliminated. To minimize that risk, study records will be kept in restricted areas at Joslin and computer access will be restricted by a password known only to authorized members of the staff at the Joslin Diabetes Center. Information that could identify me, such as name, will be maintained in a file separated from all study information.

In spite of these efforts to protect the confidentiality of information about me there is a risk that sensitive information may be obtained by others or discovered or inferred by members of my family. For example, a court of law may order Joslin to release confidential information about me.

The results of this study may be published in scientific journals or presented at medical meetings, but my identity will remain confidential.

If I wish I may also contact the Committee on Human Studies of the Joslin Diabetes Center or the Committee on the Use of Humans as Experimental Subjects at MIT. The names and telephone numbers of the Committee on Human Studies representatives are listed on the next page of this form. The Committee on the Use of Humans as Experimental Subjects can be contacted at the Chairman of the Committee on the Use of Humans as Experimental Subjects, M.I.T., Room E32-335, 77 Massachusetts Ave, Cambridge, MA 02139, phone 1-617-253 6787.

Joslin Diabetes Center, Informed Consent FormForm Revised 5/98

I have been informed of and understand the purpose of the above-described project and its procedures. I also have been informed of and understand the foreseeable discomfort, risks, and benefits. I have further been advised that unforeseen effects may occur. I understand that I may or may not be entitled to free medical care or compensation in the event that I am injured as a result of my participation in this study. I am encouraged to discuss my participation in this study with my primary care Physician.

I have been informed of and understand that the data collected in this study may be published or otherwise disseminated for scientific purposes. However, I also understand that my name will not be published and that every effort will be made to protect my confidentiality. I understand that in the event this research project results in the development of any marketable product, it is not expected that any profits would be shared with me.

I further understand that I may withdraw from the study or omit any procedure at any time without prejudice to me.

I voluntarily consent to participate in this study and have received a copy of this form.

I understand that no one has contacted my primary care physician or any other doctor from whom I may be receiving care regarding my involvement in this study. I understand that I may consult with any such doctor prior to enrolling in this study to discuss whether there is any reason he or she is aware of why I should not enroll in the study.

I have been informed of and understand that I have access to the Committee on Human Studies of the Joslin Diabetes Center if I have questions regarding my rights as a research subject on this study, through its Chairman or Administrative Representative to the Committee, whose names are listed below. I further understand that the Committee may have access to me and/or data collected in order to assist in its proper functions.

Leigh A. Read
CHS Coordinator
Telephone: (617) 732-2543

James L. Rosenzweig, M.D.
Chairman, CHS
Telephone: (617) 732-2645

Signature of Subject or
Subject's Representative

Date

Relationship to Subject
(parent, sibling, guardian)

This Portion to be Completed by Investigator (or Representative):

I have explained to the above-named subject the nature and purpose of the procedures described above and such foreseeable discomfort, risks, and benefits that may result. I have considered and rejected alternative procedures for obtaining this information. I have asked the subject if any questions have arisen regarding the procedures and have answered these questions to the best of my ability.

Signature of Investigator (or Representative)

Date

CONSENT FORM ADDENDUM

AUTHORIZATION (CONSENT) TO PERMIT THE USE AND DISCLOSURE OF IDENTIFIABLE MEDICAL INFORMATION (PROTECTED HEALTH INFORMATION) FOR RESEARCH PURPOSES

Principal Investigator: Katie Weinger, EdD
Co-Investigator(s): Akshay Mohan, B.Tech
Project Title: Effective Feedback and Visualization Tools for Diabetes

Why is my additional consent being requested?

You have previously given your consent to participate in the above-named research study. The purpose of this additional consent form is to provide you with specific information about the use and disclosure of your identifiable medical information for the purpose of this research study.

While much of this information was given to you previously, recently enacted laws focused on the privacy of medical record information require that this information be given to you in a certain way.

Through the use of this additional consent form, we are seeking your authorization (consent) for the use and disclosure of your identifiable medical information for the purpose of this research study as per the requirements addressed in these recently enacted laws.

You will also receive the Joslin Diabetes Center's Notices of Privacy Practices document, which provides more information on how the Joslin can use and disclose identifiable medical information. If you have not received the Joslin Privacy Practice document, please ask a member the study staff.

What uses of my identifiable medical record information will this research study involve?

This research study may involve the recording of identifiable medical information already in your medical record here at Joslin and/or in other health care provider's (e.g., primary care physician, hospital) records or identifiable medical information recorded in your records in the future.

The information that will be recorded will be limited to information concerning the subject's HBA1c value. This information will be used for the purpose of this research study (this information is listed in the consent form you previously signed prior to your participation in this study).

This research study may also generate new identifiable information that will be recorded in your research record kept at the Joslin Diabetes Center. The nature of the identifiable information resulting from your participation in this research study that will be recorded in your research record includes demographic information.

Who will have access to my identifiable medical record information related to my participation in this research study?

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to your identifiable medical record information recorded for, or resulting from, your participation in this research study:

- Authorized representatives of the Joslin Diabetes Center Office of Institutional Compliance;
- Other medical centers / institutions / Investigators outside the Joslin Diabetes Center participating in this research.
- The sponsor of the study, or its agents, such as data repositories or contract research organizations;
- Federal and state agencies that have authority over research, Joslin Diabetes Center or patients (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, the Office of Human Research Protections, the Department of Social Services or other governmental agencies as required by law);
- Hospital and other accrediting agencies;
- A data safety monitoring board, if applicable;
- Clinical staff not involved in the study who may become involved in your care, if it is potentially relevant to treatment;
- Your health care insurer or payer, if necessary, in order to secure their payment for any covered treatment not paid for through the study.

All reasonable efforts will be used to protect the confidentiality of your identifiable information which may be shared with others to conduct this research, to carry out their responsibilities, to conduct public health reporting and to comply with the law as applicable. Those who receive the identifiable information may share it with others if they are required by law and they may share it with others who may not need to follow these privacy rules.

May I have access to my medical record information resulting from participation in this research study?

Except for certain legal limitations, you are permitted access to any identifiable medical record information recorded for, or resulting from, your participation in this research study. You may access this information only after the study is completed.

May I refuse to provide my authorization (consent) for the use of my identifiable medical record information for the purpose of this research study?

Your authorization (consent) to use and disclose your identifiable medical record information for the purpose of this research study is completely voluntary. However, if you do not provide your written authorization (consent) for the use and disclosure of your identifiable medical record information, you will not be allowed to participate or continue to participate in the research study.

Whether or not you provide your authorization (consent) for the research use and disclosure of your medical record information will have no affect on your current or future medical care at the Joslin Diabetes Center or your current or future relationship with a healthcare insurance provider. Whether or not you provide this written authorization (consent) will have no affect on your current or future relationship with the Joslin Diabetes Center.

May I withdraw, at a future date, my authorization (consent) for the use of my identifiable medical record information for the purpose of this research study?

You may withdraw, at any time, your authorization (consent) for the use and disclosure of your identifiable medical record information for the purpose of this research study. Any identifiable medical record information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your authorization may continue to be used and disclosed by the investigators for the purposes of this research study.

To formally withdraw your authorization (consent) you should provide a written and dated notice of this decision to the principal investigator of this research study at the address on the last page of this form. Your decision to withdraw your authorization (consent) for the research use and disclosure of your medical record information will have no affect on your current or future medical care at the Joslin Diabetes Center or your current or future relationship with a health care insurance provider. Your decision to withdraw this authorization will have no affect on your current or future relationship with the Joslin Diabetes Center.

For how long will the investigators be permitted to use my identifiable medical record information?

The investigators may continue to use and disclose your identifiable medical record information for the purposes described above for an indefinite period of time. This is because information that is collected for the purposes of this study will continue to be analyzed for many years and it is not possible to determine when this will be complete.

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that, throughout my participation in this research study, I am encouraged to ask any additional questions I may have about the research use and disclosure of my identifiable medical record information. Such future questions will be answered by the investigators listed on the first page of this form.

Any questions I have about my rights associated with the research use of my medical record information will be answered by the Joslin Diabetes Center's Office of Institutional Compliance at 617-732-2531 or by email to renata.matsson@joslin.harvard.edu

By signing this form, I agree to allow the use and disclosure of my medical record information for the purposes described above. A copy of this authorization (consent) form will be given to me.

Signature of Subject

Date

For children (age < 18 years old) or adults determined to be impaired in the decision making and thus unable to provide direct authorization for the use of their identifiable medical record information.

Subject's Name (Print)

The above-named individual is unable to provide direct authorization for the use and disclosure of his/her identifiable medical record information for the purpose of this research study because:

Therefore, by signing this form, I give permission for the use and disclosure of his/her medical record information for the purpose of this research study.

Representative's Name (Print)

Representative's Relationship to Participant

Signature of Representative

Date

March 2003

CHS #: 04-11
Date: 4/15/04

VERIFICATION OF EXPLANATION

I certify that I have explained the nature and purpose of the research use and disclosure of the above-named individual's identifiable medical record information in appropriate language. He/she has had an opportunity to discuss this with me in detail. I have answered all his/her questions and he/she has provided affirmative agreement (i.e. assent) to allow the use and disclosure of his/her identifiable medical record information for the purpose of this research study.

Signature of Investigator or Investigator's Representative

Date

Investigator or Investigator's Representative (Print)

Written Correspondences should be sent to:

Katie Weinger
Joslin Diabetes Center
One Joslin Place
Boston, MA 02215

The Appendix provides the different study instruments used for the Health-Zero Diabetes Orb Study. The study instruments were provided to the participants at baseline and followup.

ID# _____ Form _____ Date _____

Baseline Report

1. Marital Status? single married separated divorced widowed Race: _____
 1 2 3 4 5

2. Occupation: _____ Gender: M F Ethnicity: _____
Age: _____

3. Circle the last year of school completed: _____
Grade School High School College Graduate/Professional
1 2 3 4 5 6 7 8 9 10 11 12 1 2 3 4 _____

4. How many people do you live with *not including you*? _____
If 1 or more, who? _____

5. How acquainted are you with the use of computers?
None at All Basic User Advanced User Expert User

6. Which of the following electronic devices do you use (please circle all that applies)?
Cell Phone PDA Digital Camera MP3 Player Laptop

7. Circle the type of diabetes you have
Type 1 Diabetes Type 2 Diabetes (Use Insulin) Type 2 Diabetes (Do Not Use Insulin)

8. Date of diagnosis of diabetes _____

9. In the past 2 weeks, how many times *per day* have you been checking your blood sugar? _____

10. Have you ever been diagnosed with any complications of diabetes? ☐ no ☐ yes
If yes, what have you been diagnosed with? _____

11. Is coping with diabetes a problem for you? ☐ no ☐ yes

12. Are you an organized person? ☐ no ☐ yes

13. Are your closets neat and organized? ☐ no ☐ yes

14. Do you do a good job managing your time? ☐ no ☐ yes

15. Do you *fully* understand your treatment plan recommendations for:

	no	yes
glucose monitoring	_____	_____
exercise	_____	_____
medication	_____	_____
meal plan	_____	_____
medical appointments	_____	_____
treating lows	_____	_____ (NA)

Appendix G2 – Self Care Inventory

ID# _____ Form _____

Date _____

Self-Care Inventory

This survey measures what you actually do, not what you are advised to do. How have you followed your diabetes treatment plan in the past 1-2 months?

	Never ▼	Rarely ▼	Sometimes ▼	Usually ▼	Always ▼	
1. Check blood glucose with monitor	1	2	3	4	5	
2. Record blood glucose results	1	2	3	4	5	
3. Look at blood glucose patterns	1	2	3	4	5	
4. If type 1: Check ketones when glucose level is high	1	2	3	4	5	Have type 2 diabetes
5. Take the correct dose of diabetes pills or insulin	1	2	3	4	5	Not taking diabetes pills or insulin
6. Take diabetes pills or insulin at the right time	1	2	3	4	5	Not taking diabetes pills or insulin
7. Eat the correct food portions	1	2	3	4	5	
8. Eat meals/snacks on time	1	2	3	4	5	
9. Keep food records	1	2	3	4	5	
10. Read food labels	1	2	3	4	5	
11. Treat low blood glucose with just the recommended amount of carbohydrate	1	2	3	4	5	Never had low blood glucose
12. Carry quick acting sugar to treat low blood glucose	1	2	3	4	5	
13. Come in for clinic appointments	1	2	3	4	5	
14. Wear a Medic Alert ID	1	2	3	4	5	
15. Exercise	1	2	3	4	5	
16. If on insulin: Adjust insulin dosage based on glucose values, food, and exercise	1	2	3	4	5	Not on insulin
17. Check feet daily	1	2	3	4	5	

Appendix G3 – Perceived Social Support

ID# _____ Form _____

Date _____

We are interested in how you feel about the following statements. Read each statement carefully. Indicate how you feel about each statement by circling the appropriate response.

	Very Strongly Disagree	Strongly Disagree	Mildly Disagree	Neutral	Mildly Agree	Strongly Agree	Very Strongly Agree
1. There is a special person who is around when I am in need	1	2	3	4	5	6	7
2. There is a special person with whom I can share joys and sorrows	1	2	3	4	5	6	7
3. My family really tries to help me	1	2	3	4	5	6	7
4. I get the emotional help and support I need from my family	1	2	3	4	5	6	7
5. I have a special person who is a real source of comfort to me	1	2	3	4	5	6	7
6. My friend really try to help me	1	2	3	4	5	6	7
7. I can count on my friends when things go wrong	1	2	3	4	5	6	7
8. I can talk about my problems with my family	1	2	3	4	5	6	7
9. I have friends with whom I can share my joys and sorrows	1	2	3	4	5	6	7
10. There is a special person in my life who cares about my feelings	1	2	3	4	5	6	7
11. My family is willing to help me make decisions	1	2	3	4	5	6	7
12. I can talk about my problems with my friends	1	2	3	4	5	6	7

Appendix G4 – Personal Health-Zero Orb Device Usage Questionnaire

ID# _____ Form _____

Date _____

Device Usage

Please indicate whether the Health-Zero was helpful for your diabetes self-management by circling the response that most closely matches your feelings.

1. How did you feel about the orb?	Loved it	Liked it	No Opinion	Annoyed me	Hated it
2. Did the orb remind you of your blood glucose level?	Never	Rarely	Sometimes	Usually	Always
3. Did you find the orb helpful in taking care of your diabetes in general?	Very useful	Useful	Not Useful	Got in the way	
4. Did the orb influence your diabetes behavior by:					
Reminding you to make better food choices?	Helped A Lot	Helped	Did Not Help	Got In The Way	
Reminding you to take your medicine and insulin?	Helped A Lot	Helped	Did Not Help	Got In The Way	
Reminding you to increase your activity?	Helped A Lot	Helped	Did Not Help	Got In The Way	
Reminding you to check your blood glucose?	Helped A Lot	Helped	Did Not Help	Got In The Way	
5. Was the orb was fun?	Never	Rarely	Sometimes	Usually	Always
6. Was the orb was useful?	Very Useful	Useful	Not Useful	Got in the way	
7. How often did you look at the orb?	Never	Rarely	Sometimes	Usually	Always
8. How difficult was it for you to interpret the colors on the orb for your blood sugar level?	Very Hard	Hard	Normal	Easy	Very Easy
9. Did visitors ask you about the orb?	Never	Rarely	Sometimes	Usually	Always

10. Where did you place the orb?

11. In what ways was the orb useful to you?

12. What did your family and/or friends think about the orb?

13. Was the orb easy to install?

14. Did you have any problems using the orb?

15. Do you have any suggestions to improve the orb and its usefulness?

Interview with the co-investigator: The co-investigator will write down the subject's response to the questions below:

- Any other stories or experiences that you wish to share regarding the use of the device?

Appendix G5 – Friend or Family Health-Zero Orb Device Usage Questionnaire

ID# _____ Form _____

Date _____

Device Usage – Friend or Family Member Orb

Please indicate whether the Health-Zero orb present with your friend or family member was helpful for your diabetes self-management by circling the response that most closely matches your feelings.

1. How did your friend or family feel about their orb?	Loved it	Liked it	No Opinion	Annoyed me	Hated it
2. Do you feel the orb helped your friend or family know your blood glucose level better?	Helped A Lot	Helped	Did Not Help	Got In The Way	
3. Did the orb in general increase the amount of help your friend or family gave you in taking care of your diabetes?	Helped A Lot	Helped	Did Not Help	Got In The Way	
4. Did the orb influence the way your friend or family helped you in your diabetes self-care in:					
Reminding you to make better food choices?	Helped A Lot	Helped	Did Not Help	Got In The Way	
Reminding you to take your medicine and insulin?	Helped A Lot	Helped	Did Not Help	Got In The Way	
Reminding you to increase your activity?	Helped A Lot	Helped	Did Not Help	Got In The Way	
Reminding you to check your blood glucose?	Helped A Lot	Helped	Did Not Help	Got In The Way	
5. Do you feel the orb was fun to use by your friend or family?	Never	Rarely	Sometimes	Usually	Always
6. Did you find your friend or family's orb useful?	Very Useful	Useful	Not Useful	Got in the way	
7. How often do you think your friend or family looked at their orb?	Never	Rarely	Sometimes	Usually	Always
8. Did your friend or family member's orb influence your diabetes self-care by:					
Reminding you to make better food choices?	Helped A Lot	Helped	Did Not Help	Got In The Way	
Reminding you to take your medicine and insulin?	Helped A Lot	Helped	Did Not Help	Got In The Way	
Reminding you to increase your activity?	Helped A Lot	Helped	Did Not Help	Got In The Way	
Reminding you to check your blood glucose?	Helped A Lot	Helped	Did Not Help	Got In The Way	

9. Where did your friend or family member place the orb (if you know the answer)?

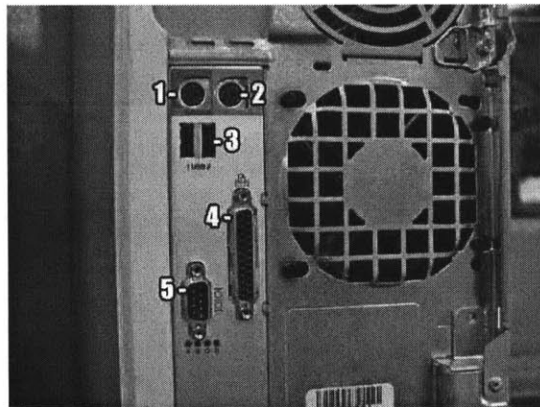
10. What did your family and/or friends think about their orb?

11. How do you feel about your friend or family member knowing your blood sugar level through with their orb?

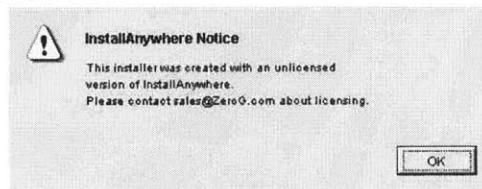
Appendix H: Study Installation Instructions

Installation Instructions for the Joslin Diabetes Orb Study

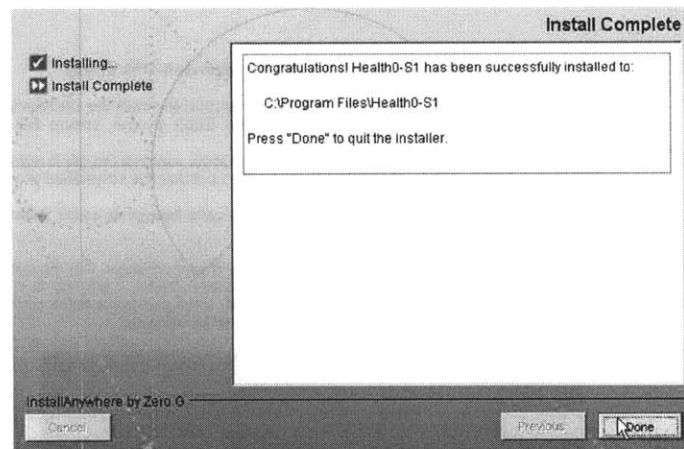
1. Before starting installation, check your blood glucose at least once with the LifeScan Ultra glucose meter provided to you. After checking your blood glucose, ensure that the glucose meter is switched off.
2. Choose an appropriate place for the Health-Zero orb. Make sure that the orb is not near water or heat (stove, radiator, heating vents, irons etc.) and that it is somewhere you can see it.
3. Plug-in the power cord of the Health-Zero orb. It will cycle through its colors indicating that it is connecting.
4. Plug-in the power cord of Device 1 (blue)
5. Attach Device 1 to the serial port (COM1), connector 5 of your computer. See the picture. Your computer's serial port may be in a different location. Device 1 will only fit into a serial port. If there are multiple such connectors, COM1 is the port that is to the extreme left or the topmost when you are looking at the back of the computer.



6. Attach Device 2 (Red Tag) to the bottom of the LifeScan Ultra glucose meter. DO NOT turn on the meter yet!
7. Insert the CD provided to you in your CD ROM drive. The installation procedure will automatically start. It may take up to one minute for the installation procedure to start.
8. Click 'OK' in the Alert window.



9. Click 'Done'

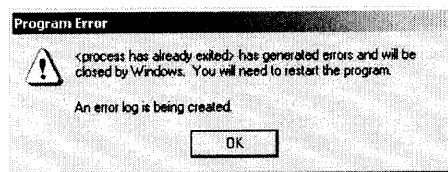


10. After a few minutes, the orb should stop cycling through its colors and settle on one of the colors as mentioned in the instruction sheet provided to you.
11. You may use your meter as usual.

For help with the installation, contact the study coordinator Akshay Mohan at akshay.mohan@joslin.harvard.edu or at (978) 432 9069

Instructions for During the Study

1. The program automatically starts itself.
2. The program only works if you have the computer switched on. In case of multiple users on your computer, it is sufficient that anyone of the users is logged in.
3. The program is able to update the reading only if the glucose meter is attached to device 2 (Bluetooth module for the glucose meter) and is within 30 feet of the computer on which you have installed the Health0 program and Device 1 to the serial port. To ensure this, if you are at home, keep your LifeScan Ultra glucose meter in the same room as the computer.
4. If the program was not able to connect to the glucose meter for 24 hours or if there was an unexpected error in the program, a display message would inform you of the error. In case you were away from your computer for more than 24 hours, continue as usual else contact the study coordinator Akshay Mohan at (978) 423 9069 in such a situation.
5. **IMPORTANT:** The computer SHOULD NOT be switched off or be in standby or hibernation mode during the study. If you switch the computer off, then it is important that you log on your computer as soon as it reboots. In case of reboot, an error screen will be displayed, press 'OK'.



Instructions at the End of the study (After 15 Days of Use)

1. Bring all equipment to your second study visit to the Joslin Diabetes Center. The glucose meter would be returned to you after its memory has been downloaded.
2. You will be provided with instructions for uninstalling the Health0 program.

Study Contact

Akshay Mohan
akshay.mohan@joslin.harvard.edu
(978) 423 9069

Installation Instructions for the Joslin Diabetes Orb Study: Family Health Zero Orb

1. Choose an appropriate place for the Health-Zero orb. Make sure that the orb is not near water or heat (stove, radiator, heating vents, irons etc.) and that it is somewhere you can see it.
2. Plug-in the power cord of the Health-Zero orb. It will cycle through its colors indicating that it is connecting.
3. After a few minutes, the orb should stop cycling through its colors and settle on one of the colors as mentioned in the instruction sheet provided to you.

Incase you have any problems during the installation process, please contact the study coordinator Akshay Mohan at (978) 423 9069.

IMPORTANT
Safety Instructions for the Joslin Diabetes Orb Study:
Family Health Zero Orb

1. Do not expose the orb to rain, moisture or any other liquid.
2. Do not expose the orb to heated surfaces, heat registers, radiators, stoves or other heat producing appliances.
3. Do not remove the cover of the orb container.
4. Do not allow children to play with the orb.
5. Do not drop the orb.

IMPORTANT
Safety Instructions for the Joslin Diabetes Orb Study

1. Do not expose any of the devices to rain, moisture or any other liquid.
2. Do not expose any of the devices to heated surfaces, heat registers, radiators, stoves or other heat producing appliances.
3. Do not remove the cover of the orb container or of any of the other devices provided.
4. Do not allow children to play with the devices.
5. Do not drop the devices.

Appendix I: Study Instruction Sheets

The appendix provides the different interpretation sheets that were provided to the participants and their friend or family members for the interpretation of blood glucose levels using the color on the Health-Zero orb.







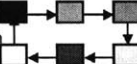
Appendix I1 – Instruction Sheet: Personal Health-Zero Orb for People with Type 1 Diabetes

Instruction Sheet – Personal Health-Zero Orb for people with type 1

The orb will change colors based on your glucose meter reading. The color of the orb is only to remind you of your blood glucose level and is not part of your diabetes treatment plan. The orb does not replace glucose monitoring, rather it simply reflects your glucose meter reading!

The color of the orb tells you whether your blood glucose was high, okay or low the last time you checked it (when you were near your computer). The colors are set to indicate a range based on general targets. Your target glucose levels may be different. Talk to your healthcare provider about your specific target blood glucose range and recommended action plan.

If the orb is blinking, then the color on the orb is based on a glucose reading that is at least 6 hours old. Recheck your blood glucose.

Color on the Orb	Blood Glucose Value	Possible Interpretation
Deep Blue 	Less than 80	Very Low Blood Glucose. Treat with 15 gm of carbohydrate (½ c soda or 3-4 glucose tabs) and recheck. Be safe and do not drive when low!
Blue 	80 – 89	Be Alert to Decreasing Blood Glucose.
Green 	90 – 139	Normal
Yellow 	140– 180	Be Alert to Increasing Blood Glucose.
Red 	More than180	Very High Blood Glucose. Take action as recommended by your healthcare provider. Check ketones as recommended.
White 	System Malfunction	Please contact the study coordinator Akshay Mohan at akshay.mohan@joslin.harvard.edu
Cycling Through Colors 	Orb Awaiting Connection	The orb is trying to connect to the network. If it continues to cycle for 5 minutes, unplug the Health-Zero orb and plug it in again







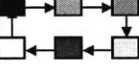
Appendix I2 – Instruction Sheet: Personal Health-Zero Orb for People with Type 2 Diabetes

Instruction Sheet – Personal Health-Zero Orb for people with type 2

The orb will change colors based on your glucose meter reading. The color of the orb is only to remind you of your blood glucose level and is not part of your diabetes treatment plan. The orb does not replace glucose monitoring, rather it simply reflects your glucose meter reading!

The color of the orb tells you whether your blood glucose was high, okay or low the last time you checked it (when you were near your computer). The colors are set to indicate a range based on general targets. Your target glucose levels may be different. Talk to your healthcare provider about your specific target blood glucose range and recommended action plan.

If the orb is blinking, then the color on the orb is based on a glucose reading that is at least 6 hours old. Recheck your blood glucose.

Color on the Orb	Blood Glucose Value	Possible Interpretation
Deep Blue 	Less than 80	Very Low Blood Glucose. Treat with 15 gm of carbohydrate (½ c soda or 3-4 glucose tabs) and recheck. Be safe and do not drive when low!
Blue 	80 – 89	Be Alert to Decreasing Blood Glucose.
Green 	90 – 139	Normal
Yellow 	140– 180	Be Alert to Increasing Blood Glucose.
Red 	More than 180	High Blood Glucose. Take action as recommended by your healthcare provider. If high for 3 days, call your provider.
White 	System Malfunction	Please contact the study coordinator Akshay Mohan at akshay.mohan@oslin.harvard.edu
Cycling Through Colors 	Orb Awaiting Connection	The orb is trying to connect to the network. If it continues to cycle for 5 minutes, unplug the Health-Zero orb and plug it in again







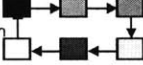
Appendix I3 – Instruction Sheet for Family Health-Zero Orb for People with Type 1 Diabetes

If a study participant chose to give a second Health-Zero orb to a friend or family member, he or she was provided with another interpretation sheet to be given to them. The friend or family member was also given a copy of the instruction sheet provided to the study participants.

Instruction Sheet – Family Health-Zero Orb for people with type 1

The orb will change colors based on the glucose meter reading of your family member (or friend). The color of the orb informs you of your family member's blood glucose level: whether it was high, okay or low the last time it was checked. The orb only works when your family member is at home. The colors indicate a range based on general blood glucose targets and not necessarily your family member's target glucose levels. If the orb is blinking, then the color on the orb is based on a glucose reading that is at least 6 hours old.

The next page provides the instruction sheet that has been provided to your friend and family member for his orb

Color on the Orb	Blood Glucose Value	Possible Interpretation
Deep Blue 	Less than 80	Very Low Blood Glucose.
Blue 	80 – 89	Blood Glucose Decreasing.
Green 	90 – 139	Normal
Yellow 	140– 180	Blood Glucose Increasing.
Red 	More than 180	Very High Blood Glucose.
White 	System Malfunction	Please ask your friend or family member to contact the study coordinator Akshay Mohan at akshay.mohan@joslin.harvard.edu
Cycling Through Colors 	Orb Awaiting Connection	The orb is trying to connect to the network. If it continues to cycle for 5 minutes, unplug the Health-Zero orb and plug it in again







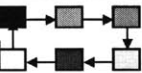
Appendix I4 – Instruction Sheet for Family Health-Zero Orb for People with Type 2 Diabetes

Instruction Sheet – Personal Health-Zero Orb for people with type 2

The orb will change colors based on your glucose meter reading. The color of the orb is only to remind you of your blood glucose level and is not part of your diabetes treatment plan. The orb does not replace glucose monitoring, rather it simply reflects your glucose meter reading!

The color of the orb tells you whether your blood glucose was high, okay or low the last time you checked it (when you were near your computer). The colors are set to indicate a range based on general targets. Your target glucose levels may be different. Talk to your healthcare provider about your specific target blood glucose range and recommended action plan.

If the orb is blinking, then the color on the orb is based on a glucose reading that is at least 6 hours old. Recheck your blood glucose.

Color on the Orb	Blood Glucose Value	Possible Interpretation
Deep Blue 	Less than 80	Very Low Blood Glucose. Treat with 15 gm of carbohydrate (½ c soda or 3-4 glucose tabs) and recheck. Be safe and do not drive when low!
Blue 	80 – 89	Be Alert to Decreasing Blood Glucose.
Green 	90 – 139	Normal
Yellow 	140– 180	Be Alert to Increasing Blood Glucose.
Red 	More than 180	High Blood Glucose. Take action as recommended by your healthcare provider. If high for 3 days, call your provider.
White 	System Malfunction	Please contact the study coordinator Akshay Mohan at akshay.mohan@joslin.harvard.edu
Cycling Through Colors 	Orb Awaiting Connection	The orb is trying to connect to the network. If it continues to cycle for 5 minutes, unplug the Health-Zero orb and plug it in again

Appendix J: Participants Response to Selected Questionnaires

This appendix provides the responses of the study participants to the device usage questionnaires: the personal Health-Zero Orb and the family Health-Zero Orb. Only the results of the objective questions have been included. Appendix J1 lists the response to the personal health-zero orb device usage questionnaire. Appendix J2 lists the response to the family health-zero orb device usage questionnaire.

Appendix J1 – Response to the Personal Health-Zero Orb Device Usage Questionnaire

1. How did you feel about the orb?	Loved It	Liked It	No Opinion	Annoyed Me	Hated It
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Did the orb remind you of your blood glucose level?	Never	Rarely	Sometimes	Usually	Always
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Did you find the orb helpful in taking care of your diabetes in general?	Very Useful	Useful	Not Useful	Got In The Way	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4. Did the orb influence your diabetes self-care by:					
Reminding you to make better food choices?	Helped A Lot	Helped	Did Not Help	Got In The Way	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Reminding you to take your medicine and insulin?	Helped A Lot	Helped	Did Not Help	Got In The Way	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Reminding you to increase your activity?	Helped A Lot	Helped	Did Not Help	Got In The Way	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Reminding you to check your blood glucose?	Helped A Lot	Helped	Did Not Help	Got In The Way	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5. Was the orb fun to use?	Never	Rarely	Sometimes	Usually	Always
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Was the orb useful?	Very Useful	Useful	Not Useful	Got In The Way	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7. How often did you look at the orb?	Never	Rarely	Sometimes	Usually	Always
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. How difficult was it for you to interpret the colors on the orb for your blood sugar level?	Very Hard	Hard	Normal	Easy	Very Easy
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Did visitors ask you about the orb?	Never	Rarely	Sometimes	Usually	Always
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Appendix J2 – Response to the Family Health-Zero Orb Device Usage Questionnaire

1. How did your friend or family feel about their orb?	Loved It	Liked It	No Opinion	Annoyed Me	Hated It
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			
2. Do you feel the orb helped your friend or family member know your blood glucose level better?	Helped A Lot	Helped	Did Not Help	Got In The Way	
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			
3. Did the orb in general increase the amount of help your friend or family member gave you in taking care of your diabetes?	Helped A Lot	Helped	Did Not Help	Got In The Way	
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		
4. Did the orb influence the way your friend or family helped you in your diabetes self-care in:					
Reminding you to make better food choices?	Helped A Lot	Helped	Did Not Help	Got In The Way	
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		
Reminding you to take your medicine and insulin?	Helped A Lot	Helped	Did Not Help	Got In The Way	
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		
Reminding you to increase your activity?	Helped A Lot	Helped	Did Not Help	Got In The Way	
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		
Reminding you to check your blood glucose?	Helped A Lot	Helped	Did Not Help	Got In The Way	
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		
5. Do you feel the orb was fun to use by your friend or family?	Never	Rarely	Sometimes	Usually	Always
				<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
6. Did you find your friend or family's orb useful?	Very Useful	Useful	Not Useful	Got In The Way	
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			
7. How often do you think your friend or family looked at their orb?	Never	Rarely	Sometimes	Usually	Always
				<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

8. Did your friend or family member's orb influence your diabetes self-care by:					
Reminding you to make better food choices?	Helped A Lot	Helped	Did Not Help	Got In The Way	
Reminding you to take your medicine and insulin?	Helped A Lot	Helped	Did Not Help	Got In The Way	
Reminding you to increase your activity?	Helped A Lot	Helped	Did Not Help	Got In The Way	
Reminding you to check your blood glucose?	Helped A Lot	Helped	Did Not Help	Got In The Way	

Appendix K: Clinical Information for Diabetes

What is Diabetes

Diabetes is a disorder of metabolism--the way our bodies use digested food for growth and energy. Most of the food we eat is broken down into glucose, the form of sugar in the blood. Glucose is the main source of fuel for the body. After digestion, glucose passes into the bloodstream, where it is used by cells for growth and energy. For glucose to get into cells, insulin must be present. Insulin is a hormone produced by the pancreas, a large gland behind the stomach. When we eat, the pancreas automatically produces the right amount of insulin to move glucose from blood into our cells. In people with diabetes, however, either the pancreas produces little or no insulin, or the cells do not respond appropriately to the insulin that is produced. Glucose builds up in the blood, overflows into the urine, and passes out of the body. Thus, the body loses its main source of fuel even though the blood contains large amounts of glucose.

What are the types of Diabetes

The three main types of diabetes are: type 1 diabetes, type 2 diabetes and gestational diabetes.

Type 1 diabetes is an autoimmune disease. An autoimmune disease results when the body's system for fighting infection (the immune system) turns against a part of the body. In diabetes, the immune system attacks the insulin-producing beta cells in the pancreas and destroys them. The pancreas then produces little or no insulin. A person who has type 1 diabetes must take insulin daily to live

The most common form of diabetes is type 2 diabetes. About 90 to 95 percent of people with diabetes have type 2. This form of diabetes is associated with older age, obesity, family history of diabetes, previous history of gestational diabetes, physical inactivity, and ethnicity. When type 2 diabetes is diagnosed, the pancreas is usually producing enough insulin, but for unknown reasons, the body cannot use the insulin effectively, a condition called insulin resistance. After several years, insulin production decreases

Gestational diabetes develops only during pregnancy. Like type 2 diabetes, it occurs more often in African Americans, American Indians, Hispanic Americans, and among women with a family history of diabetes. Women who have had gestational diabetes have a 20 to 50 percent chance of developing type 2 diabetes within 5 to 10 years.

How is diabetes managed?

Healthy eating, physical activity, and taking insulin via injection or an insulin pump are the basic therapies for type 1 diabetes. The amount of insulin must be balanced with food intake and daily activities. Blood glucose levels must be closely monitored through frequent blood glucose checking. Healthy eating, physical activity, and blood glucose testing are the basic management tools for type 2 diabetes. In addition, many people with type 2 diabetes require oral medication, insulin, or both to control their blood glucose levels. People with diabetes must take responsibility for their day-to-day care. Much of the daily care involves keeping blood glucose levels from going too low or too high. When blood glucose levels drop too low--a condition known as hypoglycemia--a person can become nervous, shaky, and confused. Judgment can be impaired, and if blood glucose falls too low, fainting can occur. A person can also become ill if blood glucose levels rise too high, a condition known as hyperglycemia. The goal of diabetes management is to keep blood glucose levels as close to the normal range as safely possible.

Diabetes Measurements

HBA1c Test

The test measures the amount of hemoglobin that carries glucose molecules. By measuring A1C, you get an idea of the average amount of glucose in your blood over the last few months. As glucose circulates in your blood, some of it spontaneously binds to hemoglobin (the red protein that carries oxygen in your red blood cells). This combination is called hemoglobin A1c (A1C). The amount of A1C formed is directly related to the amount of glucose in your blood. If your diabetes is not well controlled, your blood glucose levels are high, causing higher A1C levels. A1C levels do not change quickly since red cells live for 2–3 months. Because of this, the amount of A1C in the blood reflects the average amount of glucose in the blood during the last few months.

Blood Glucose Testing

Glucose is a monosaccharide, a simple sugar that serves as the main source of energy for the body. A blood sample is obtained by inserting a needle into a vein in the arm, or a drop of blood is taken from your finger by pricking it with a small pointed lancet. This blood sample is then used for the measurement of the blood glucose level using a glucose meter. The glucose test is a snapshot, a still photograph of a moving picture. It tells what the blood glucose level was at the moment it was collected.

References

National Diabetes Information Clearinghouse
<http://diabetes.niddk.nih.gov/>

Appendix L: Information about ECG

The electrocardiogram (ECG) is the potential developed by the heart and measured on the body-surface. Several 'waves' occur within each heartbeat. The waves are labeled P, QRS, and T and correspond to electrical activity when the heart's artria contract (P), the ventricls contract (QRS) and when the ventricls repolarize (T). The QRS complex duration is about 80 milliseconds. Typically, it has an amplitude of about 1 mVp-p. The P-wave has amplitude of about 100 microvolts. The wave-complex repeats with each heartbeat. A typical ECG is shown in the figure L-1

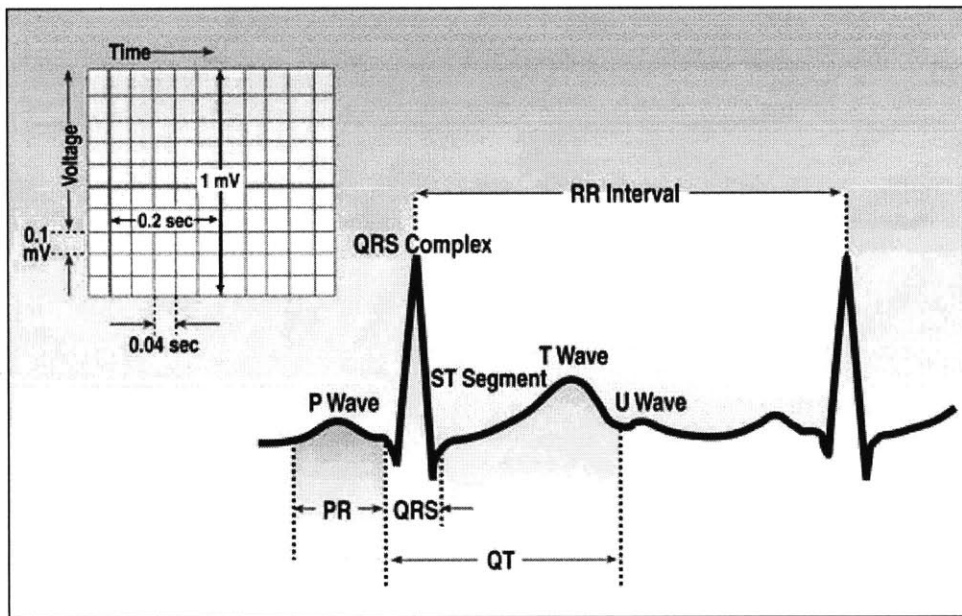


Figure L-1 A ECG Waveform and the different waves. The figure also shows the ECG paper on which the an ECG is recorded
(source: University of Utah School of Medicine)